KENTUCKY PANDEMIC INFLUENZA OPERATIONS PLAN
LABORATORY AND SURVEILLANCE SUPPLEMENT

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This supplement provides guidance on surveillance and laboratory activities during the various phases of pandemic.

I. RATIONALE/OVERVIEW

Surveillance for pandemic influenza centers around four major issues that will vary in importance depending on the pandemic phase: (1) to respond to every individual case to limit the spread of disease; (2) to respond to clusters or upward trends or outbreaks; (3) to provide information to plan prevention programs and (4) to provide information to evaluate prevention and control programs. In order to evaluate and tailor disease control interventions of a novel virus, it will be crucial to collect and analyze detailed real-time data on its clinical and epidemiological characteristics.

An effective statewide pandemic influenza surveillance system requires a well-functioning, interpandemic influenza surveillance system. Surveillance needs will expand and change as an influenza pandemic evolves from the initial stages (i.e., when a novel influenza virus is first identified in one or more persons), to a pandemic (i.e., with efficient human-to-human transmission). Surveillance needs will differ depending on where the disease has been identified, whether there is coexisting disease among livestock or other animals, how efficiently transmission occurs between people, and whether disease outbreaks have occurred in the United States or other countries.

Disease surveillance data will be critical to guide the implementation of control measures (i.e., restricting travel, closing schools, canceling public gatherings, initiating antiviral and vaccine administration to target groups, etc.), assessing the impact of a pandemic on the healthcare system, and assessing the social and economic impact on society. In order to quickly identify a novel strain of influenza in our population, Kentucky has instituted year-round influenza surveillance as described in Appendix 1.

The goals of disease surveillance are to:

- Serve as an early warning system to detect increases in ILI in the community.
- Monitor the pandemic's impact on health (e.g., by tracking outpatient visits, hospitalizations, and deaths).
- Track trends in influenza disease activity and identify populations that are severely affected.

Diagnostic testing for pandemic influenza virus may involve a range of laboratory assays, including rapid antigen tests, reverse-transcription polymerase chain reaction (RT-PCR), virus isolation, and immunofluorescence antibody (IFA) assays. During the earliest stages of a pandemic, public health, hospital, and clinical laboratories might receive a

large and potentially overwhelming volume of clinical specimens. Pre-pandemic planning is therefore essential to ensuring the timeliness of diagnostic testing and the availability of diagnostic supplies and reagents, addressing staffing issues, and disseminating protocols for safe handling and shipping of specimens. Once a pandemic is underway, the need for laboratory confirmation of clinical diagnoses may decrease as the virus becomes widespread.

The goals of diagnostic testing during a pandemic are to:

- Identify the earliest Kentucky cases of pandemic influenza (whether the pandemic begins in the United States or elsewhere).
- Support disease surveillance to monitor the pandemic's geographic spread and impact of interventions.
- Facilitate clinical treatment by distinguishing patients with influenza from those with other respiratory illnesses.
- Monitor circulating viruses for antiviral resistance and antigenic drift or antigenic shift.

In conjunction with recommendations from other public health partners, such as the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO), the Division of Epidemiology and Health Planning (DEHP) will provide updated guidance to medical providers and LHDs on an ongoing basis. Surveillance activities outlined below will be contingent on local, national and international influenza activity at the time.

II. BASIC OPERATIONS

Key Personnel

It will be critical to maintain quick and efficient data collection, analysis, and reporting mechanisms during pandemic alert and pandemic phases. The state influenza surveillance coordinator is the lead position responsible for coordinating all activities relating to influenza surveillance. The state influenza surveillance coordinator is located in the Immunization Section of the Infectious Disease Branch in the DEHP of the Kentucky Department for Public Health (KDPH). The KDPH is organizationally located within the Cabinet for Health and Family Services (CHFS). See Appendix 7 for contact information and a list of other key personnel for pandemic influenza laboratory and surveillance activities. See Appendices 1 and 3 of the Base Plan for the organizational structure of the CHFS and KDPH.

In addition to the key personnel at the state level, the local influenza surveillance coordinators and the 18 regional epidemiologists will be instrumental in conducting enhanced surveillance and investigation of early cases and clusters of a novel strain of

influenza. See Appendix 8 for a map of the areas served by the regional epidemiologists and their contact information.

Surveillance Communications

- Human influenza reporting requirements, recommendations, clinical criteria and case definition information will be sent through established channels of communication to local health departments (LHDs), hospitals, and healthcare providers. These communication channels include the Infection Control Listserv, email, WebEOC, EMSystem and EMResource, KDPH Pandemic Influenza website: http://panflu.chfs.ky.gov, the Health Alert Network (HAN), *Kentucky Epidemiologic Notes and Reports,* conference calls, and satellite radio (when necessary).

- The KDPH possesses contact information for all LHDs and hospitals throughout Kentucky. In order to relay information to private providers, KDPH will send clinical criteria, case definitions, and reporting requirements through the Kentucky Medical Association (KMA).

- All reporting requirements, clinical criteria, case definitions, and laboratory specimen packaging and shipping instructions will be posted on the KDPH pandemic influenza website: http://panflu.chfs.ky.gov.

- The website and all disseminated information will include contact information for the state influenza surveillance coordinator, the Infectious Disease Branch, the Division of Laboratory Services (DLS), as well as a 24/7 contact number for KDPH's on-call epidemiologist: **888-9REPORT**. See Appendix 5, 6, and 7 of the Communications Supplement for a complete listing of Kentucky LHDs and hospitals.

- Electronic reporting of influenza activity will be done through the established Disease Surveillance Module (DSM) of the Kentucky Electronic Public Health Reporting System (KY-EPHRS).

- Animal surveillance for highly pathogenic strains of influenza is conducted by the Kentucky Department of Agriculture (KDA) and the Kentucky Department of Fish and Wildlife Resources (KDFWR). The KDA is responsible for surveillance of all commercial and privately-owned animals while the KDFWR is responsible for all wild animals.

- The KDPH has been working with the KDA with the development of the State Agriculture Response Team (SART). The SART is a resource that will be utilized for an emergency response to an agricultural disaster or disease outbreak. Its members include representatives from state agencies, industry, universities, volunteers, and the private sector.

- KDPH has met with the KDA to discuss pandemic influenza preparedness and establishing lines of communication to enhance animal and human surveillance for highly pathogenic avian influenza (HPAI). The KDA has a strong relationship with KDFWR and the Kentucky Poultry Federation (KPF) who have protocols and response plans for highly pathogenic avian influenza (HPAI).

- A state-wide avian influenza workshop was conducted in October 2007 which brought together state and local public health, representatives from KDA and KDFWR, and commercial poultry producers to build relationships and discuss human and animal surveillance for highly pathogenic influenza. All agencies have agreed to share surveillance information and send notifications in the event of highly pathogenic avian influenza and/or pandemic influenza.

- Contact information for the KDA and the KDFWR can be found in Appendix 3 of the Communications Supplement. The KDA and KDFWR will send animal surveillance information to the DEHP through emailing and/or faxing key personnel listed in Appendix 7.

- Contacts for mass fatality preparations have also been made, so that death surveillance can be linked with those who are involved in the disposition of the remains of pandemic victims. KDPH has been collaborating with the State Medical Examiner's Office for several years. The state's forensic anthropologist serves on the Health and Medical Preparedness Advisory Committee.

- The Kentucky Coroner's Association has been engaged in planning activities with the KDPH, such as creation of an electronic death registry, and these agencies are jointly creating mass fatality response teams.

- Information regarding novel influenza cases will be sent to the Kentucky Coroner's Association and to the Medical Examiner's Office for dissemination to all local coroners and medical examiners. The 120 coroners throughout Kentucky will be given a profile in the Health Alert Network so they can receive quick notifications from the KDPH regarding pandemic influenza and other public health emergencies. Communications from coroners will come directly to the KDPH or through the state Medical Examiner's Office and sent to the key personnel defined in Appendix 7.

III. GUIDELINES FOR INTERPANDEMIC AND PANDEMIC ALERT PERIODS

The objectives of surveillance for pandemic influenza will vary based on the phase of the pandemic.

Interpandemic Surveillance Objectives

During the interpandemic phase, sentinel surveillance throughout the state is used to assess the seasonal burden of influenza. Surveillance data is primarily used to enhance the influenza vaccination program and to identify the predominant circulating strains of influenza. Surveillance serves not only to detect local outbreaks of seasonal influenza, but also unusual clusters of illness that may be due to a new influenza virus. Influenza is not a reportable disease; however, outbreaks or clusters of any disease, including influenza, are reportable by Commonwealth of Kentucky regulation.

Interpandemic and Pandemic Alert Novel Influenza Virus Surveillance Activities

- Ensure early detection of cases and clusters of respiratory infections that might signal the presence of a novel influenza virus.
- Ensure laboratory resources are available to rapidly detect the introduction of a novel virus.
- If a novel strain of influenza is confirmed, ensure prompt and complete identification and reporting of potential cases to facilitate control and management of local outbreaks.

A. Epidemiological and Laboratory Surveillance for Human Infection

During WHO Pandemic Phases 1 and 2 (Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals), the DEHP will:

- Continue all interpandemic influenza surveillance activities as described in Appendix 1.

- Encourage influenza sentinel providers and health departments to perform year-round reporting of ILI activity.

- In conjunction with LHDs and the Kentucky Hospital Association (KHA), work closely with healthcare organizations and healthcare providers to implement active surveillance in emergency departments, inpatient wards, and intensive care units and explore developing an enhanced surveillance system for pneumonia and influenza-associated hospitalizations.

- Continue the planned implementation of WebEOC in the KDPH, LHDs, and hospitals throughout Kentucky. WebEOC will permit exchange of de-identified information regarding influenza and pneumonia-related hospitalizations and deaths.

- In conjunction with LHDs and hospitals, work with state and local medical examiners and coroners to establish lines of communication and explore developing an enhanced surveillance system for influenza and pneumonia-related

deaths. Register all coroners and medical examiners on KY Health Alert Network (HAN) and create a medical examiner and coroner listserv.

- Continue working with the FEMA Region IV Planning Coalition to establish mass fatality teams.

- Continue working to establish an electronic death registry.

- Encourage the use of influenza and rapid diagnostic tests, IFA assays, and PCR to detect the first cases of novel virus infection in Kentucky, and target containment strategies, such as isolation and quarantine, contact tracing, and use of limited vaccine and antivirals in the populations at risk during the interpandemic period and early stages of a pandemic, before community transmission is established.

- Request LHDs, healthcare providers, and healthcare facilities to report any suspect avian influenza cases and forward clinical specimens to the Division of Laboratory Services (DLS) for concurrent testing.

- Expand the capacity for novel virus testing among local laboratories, including providing training, technical assistance, and reference or validation testing. Request laboratories to report testing for any suspect avian influenza cases and to forward clinical specimens to the DLS for testing.

- Coordinate with the Kentucky Department for Agriculture, Kentucky Poultry Federation, and Kentucky Fish and Wildlife Resources for enhanced surveillance and reporting of novel influenza virus in poultry workers, commercial and private poultry flocks, and wild birds to identify disease activity in animal populations and to characterize the human health threat.

- Share influenza surveillance data and epidemiological information in a timely manner with LHDs, regional epidemiologists, and the CDC.

- Develop and implement criteria and protocols for epidemiologic investigation of influenza outbreaks, influenza case clusters with unusual clinical presentations, and clusters of unexplained pneumonia.

- Enhance and expand capacity at the local levels to conduct case investigations and epidemiologic investigations. These activities will include conducting an inventory of current capacity, determining current skill levels, conducting drills and exercises in case investigations, developing forecasts of future capacity needs under different pandemic scenarios, identifying gaps in capacity, and building ERRTs and Epi Strike Teams throughout the state.

- In conjunction with LHDs, evaluate and implement an outbreak management system to assist with case management, case ascertainment, case reporting, surveillance, and data analysis.

- Develop protocols that clearly designate who will conduct epidemiologic studies of novel influenza strains and coordinate between local, state, and federal investigations.

- Identify funding and training strategies to ensure that epidemiologic capacity at the state and local levels is consistent with current and future needs.

WHO Pandemic Phases 3 and 4 (Pandemic Alert Period: Human infection with no or very limited human-to-human transmission)

Investigation of Early Human Cases

- KDPH closely monitors the World Health Organization Pandemic Influenza Phases, http://pandemicflu.gov, http://www.cdc.gov/flu/weekly/fluactivity.htm, and notifications of influenza-related activity sent through Epi-X. As the threat of a pandemic escalates and progress is made into WHO phase 4, KDPH will increase communications with LHDs, local influenza surveillance coordinators, hospitals, infection control practitioners, and regional epidemiologists. Current case definitions and all contact information for KDPH and DLS will be disseminated throughout the state and posted on the KDPH Pandemic Influenza website: http://panflu.chfs.ky.gov .

- During the interpandemic and pandemic alert phases, KDPH will rely upon several different data sources to quickly identify novel strains of influenza. These sources include the Influenza Sentinel Surveillance System (Appendix 1), the Disease Surveillance Module (DSM) of the KY Electronic Public Health Records System (KY-EPHRS), and community-based surveillance systems throughout the state.
    - The DSM is a secured, electronic reporting system for notifiable diseases and conditions. Data is entered into the DSM by hospital infection control practitioners and local health departments throughout the state.

    - In addition to DSM, KDPH contracted with a software development company and hospitals in the Louisville Metro area to implement an electronic community-based surveillance system. Data is automatically collected from hospital databases based on diagnoses and analyzed for frequencies and aberrations. This system will be set to identify pneumonia and influenza-related emergency room visits and hospital admissions and is planned to expand to other highly populated areas of the state such as central, northern, and eastern Kentucky in 2008 and 2009. The community-based surveillance system will also be linked to BioSense

through several select hospitals in the Louisville Metro Area in the near future. The KDPH has also been piloting Outbreak Management System (OMS) within the next few months.

- Local influenza surveillance coordinators and regional epidemiologists will maintain daily communication with sentinel providers and local hospitals.

- If a human case of novel influenza is suspected; the local healthcare provider, local influenza surveillance coordinator, and/or regional epidemiologist will contact the state influenza surveillance coordinator or call the 24/7 contact number (if after normal business hours of Mon-Fri 8:00AM-4:30PM) for consultation and technical assistance. The local influenza surveillance coordinator or regional epidemiologist will then conduct an interview using the Human Influenza A (H5) Domestic Case Screening Form found in Appendix 3. A lab specimen will be collected, packaged, and shipped to the Division of Laboratory Services (DLS) according to Appendices 2 and 6. The Centers for Disease Control and Prevention (CDC) will be notified.

- If the suspected case meets the case definition, the individual may be isolated and the local Epi Rapid Response Team (ERRT) will be activated. All contacts of the case in question may be quarantined. All confirmed cases, suspected cases, and contacts will be closely monitored. KDPH's Department Operations Center (DOC) may be activated and the LHD DOC may be activated.

- If the presence of a novel strain of influenza is laboratory confirmed, the local ERRT will begin active surveillance of its community/region. KDPH will activate the DOC and activate the Kentucky Pandemic Influenza Operations Plan to quickly identify cases and implement community mitigation activities.

- All LHDs, hospitals, and healthcare providers throughout Kentucky will be promptly notified through the aforementioned communication channels.

- KDPH will provide consultation and technical assistance to all counties, districts, and regions for all pandemic influenza-related health and medical activities.

- All local influenza surveillance coordinators and regional epidemiologists should work with local healthcare providers to gather information on individuals who meet clinical criteria and should ensure laboratory specimens are collected and shipped to DLS for confirmation.

- All influenza-like-illness (ILI) data will be gathered at the local and regional level and reported to the state influenza surveillance coordinator daily.

- Data for pneumonia and influenza-related hospitalizations will be collected from all KY hospitals through secured communications via EMSystem and EMTrack.

This data will be used to estimate attack rates and rates of influenza-associated hospitalizations.

- Mortality data will be gathered from local influenza surveillance coordinators, coroners and medical examiners, and the Office of Vital Statistics (OVS). Mortality data are to be matched with confirmed and suspected influenza cases to calculate case fatality rates.

- All data received at the state level will be tabulated and analyzed by epidemiologists from the DEHP.

- The state influenza coordinator will report all cases of novel influenza, attack rates, and mortality rates to the CDC on a daily basis through established channels of reporting or through other mechanisms specified by the CDC.

- In addition to tracking confirmed and suspected cases, local influenza surveillance coordinators, ERRTs, and Regional Epidemiologists will be responsible for collecting and reporting all data regarding the number of isolated and quarantined individuals within their jurisdiction to the DEHP.

- The Kentucky Office of Vital Statistics (OVS) is in the process of implementing an electronic death registry (EDR). When the registry is complete, it will be used to monitor influenza and pneumonia-related mortality.

- The Vital Statistics Branch is organizationally located in the DEHP of KDPH and can easily share mortality data with the Infectious Disease Branch and Public Health Preparedness Branch of KDPH. See Appendix 9 for the KY EDR implementation plan.

- If a pandemic begins before the EDR is complete, DEHP will use the current method for processing death certificates and download mortality data each day from the existing electronic database and calculate influenza and pneumonia-related mortality rates.

The DEHP will:

- Upon lab confirmation of the first case of novel influenza virus in Kentucky, distribute guidance to all LHDs on surveillance, case detection, contact tracing, and infection control. The DEHP will coordinate disease control activities and provide technical assistance to LHDs and healthcare facilities with any confirmed cases of novel influenza virus infection.

- Actively monitor and implement as necessary, any changes in recommendations and guidelines for surveillance and diagnostic testing from CDC (e.g., revision to the case definition, screening criteria, case report forms, or diagnostic testing

algorithms), and post a case screening form and a case report form for laboratory confirmed cases on the KDPH Pandemic Influenza website at: http://panflu.chfs.ky.gov

- Disseminate case definitions, clinical criteria, and epidemiological criteria for the evaluation of patients with possible novel influenza to all LHDs, hospitals, and healthcare providers. The current criteria is as follows:

  - During the Pandemic Alert Period, human infections with novel influenza A viruses will be uncommon. Therefore, **both clinical and epidemiologic criteria should be met**. The criteria will be updated as needed and found at www.cdc.gov/flu.

  - **Clinical criteria**
    Any suspected cases of human infection with a novel influenza virus must meet the criteria for ILI: **temperature of** >100.4°F **(>38°C) plus one of the following: sore throat, cough, or dyspnea**.

    - Because of the large number of ILI cases during a typical influenza season, during the Interpandemic and Pandemic Alert Periods laboratory evaluation for novel influenza A viruses is recommended **only** for:
      a) Hospitalized patients with severe ILI, including pneumonia, who meet the epidemiologic criteria (see below), or
      b) Non-hospitalized patients with ILI and with strong epidemiologic suspicion of novel influenza virus exposure (e.g., direct contact with ill poultry in an affected area, or close contact with a known or suspected human case of novel influenza within 10 days prior to onset of symptoms.).

    - See the Clinical Guidelines Supplement of this plan for more detailed recommendations for the evaluation of patients with respiratory illnesses.

  - **Epidemiologic criteria**
    Epidemiologic criteria for evaluation of patients with possible novel influenza focus on the **risk of exposure** to a novel influenza virus with pandemic potential. Although the incubation period for seasonal influenza ranges from 1 to 4 days, the incubation periods for novel types of influenza are currently unknown and might be longer. Therefore, the maximum interval between potential exposure and symptom onset is set conservatively at 10 days.

    - **Exposure risks** — Exposure risks fall into two categories: a) travel and b) occupational.

a) Travel risks: Persons have a travel risk if they have, within 10 days prior to onset of symptoms:

1) recently visited or lived in an area affected by highly pathogenic avian influenza A outbreaks in domestic poultry or where a human case of novel influenza has been confirmed, **and**
2) either had direct contact with poultry, **or**
3) had close contact with a person with confirmed or suspected novel influenza. Updated listings of areas affected by avian influenza A (H5N1) and other current/recent novel strains are provided on the websites of the OIE (http://www.oie.int/eng/en_index.htm), WHO (www.who.int/en/), and CDC (www.cdc.gov/flu/).

   Direct contact with poultry is defined as: 1) touching birds (well-appearing, sick, or dead), or 2) touching poultry feces or surfaces contaminated with feces, or 3) consuming uncooked poultry products (including blood) in an affected area. Close contact with a person from an infected area with confirmed or suspected novel influenza is defined as being within 3 feet (1 meter) of that person during their illness. Because specific testing for human infection with avian influenza A (H5N1) might not be locally available in an affected area, persons reporting close contact in an affected area with a person suffering from a severe, yet unexplained, respiratory illness should also be evaluated.

   Human influenza viruses circulate worldwide and year-round, including in countries with outbreaks of avian influenza A (H5N1) among poultry. Therefore, during the Interpandemic and Pandemic Alert Periods, human influenza virus infection can be a cause of ILI among returned travelers at any time of the year, including during the summer in the United States. This includes travelers returning from areas affected by poultry outbreaks of highly pathogenic avian influenza A (H5N1) in Asia. As of May 2006, such persons are currently more likely to have infection with human influenza viruses than with avian influenza A (H5N1) viruses.

b) Occupational risks

Persons at occupational risk for infection with a novel strain of influenza include:

1) persons who work on farms or live poultry markets
2) persons who process or handle poultry infected with known or suspected avian influenza viruses
3) workers in laboratories that contain live animal or novel influenza viruses
4) healthcare workers in direct contact with a suspected or confirmed novel influenza case.

Information on limiting occupational risk is provided on the Occupational Health and Safety Administration (OSHA) website at: www.osha.gov/dsg/guidance/avian-flu.html.

During the Interpandemic and Pandemic Alert Periods, when there is no sustained human-to-human transmission of any novel influenza viruses, **direct contact** with animals such as poultry in an affected area or close contact with a case of suspected or confirmed human novel influenza is **required** for further evaluation.

During the Pandemic Alert Period, Phases 3 and 4, the majority of human cases of novel influenza will result from avian-to-human transmission (see Box 1). Therefore, a history of direct contact with poultry (well-appearing, sick, or dead), consumption of uncooked poultry or poultry products, or direct exposure to environmental contamination with poultry feces in an affected area will be important to ascertain.

During the Pandemic Alert Period, Phase 5, a history of close contact with an ill person suspected or confirmed to have novel influenza in an affected area will be even more important.

Other avian influenza A viruses

Although the epidemiologic criteria for novel influenza are based on recent human cases of avian influenza A (H5N1), they are intended for use in the evaluation of suspected cases of infection with any novel influenza A virus strain.

Other avian influenza A viruses that have caused human disease include the highly pathogenic viruses H7N7 and H7N3 and the low pathogenic viruses H9N2 and H7N2. Some of these human cases have occurred in Europe (Netherlands) and North America (Canada and the United States). Therefore, the same high-risk exposures defined above for avian influenza A (H5N1) also apply to other avian influenza A viruses.

A strong epidemiologic link to an avian influenza outbreak in poultry, even in areas that have not experienced poultry outbreaks of avian influenza A (H5N1), may raise the index of suspicion for human infection with avian influenza A viruses.

In the future, other animal hosts (in addition to poultry) or novel influenza A virus subtypes (in addition to H5N1) might become significantly associated with human disease. If such events occur, this guidance will be updated.

- Communicate with LHDs, regional epidemiologists and infection control practitioners via the Infection Control Listserv, email, WebEOC (if necessary) KKDPH Pandemic Influenza website: http://panflu.chfs.ky.gov, HAN, *Kentucky Epidemiologic Notes and Reports,* and conference calls to share information on surveillance criteria, case management, specimen collection, appropriate testing, and community containment.

- In conjunction with LHDs and the Kentucky Hospital Association (KHA), continue working with healthcare organizations and healthcare providers to implement active surveillance in emergency departments, inpatient wards, and intensive care units. Develop an enhanced surveillance system for influenza and pneumonia-related hospitalizations.

- In conjunction with LHDs and hospitals, continue working with state and local medical examiners to develop an enhanced surveillance system for influenza and pneumonia-related deaths. Ensure that all medical examiners are registered in HAN and the medical examiner listserv is current.

- Continue working to establish mass fatality teams and an electronic death registry.

- Issue guidance for managing suspect novel influenza cases; including infection control guidelines, guidelines for collecting and shipping specimens for influenza A diagnostics, and laboratory biosafety guidelines for handling and processing of specimens of novel influenza A. Laboratory biosafety guidelines will be posted on the DLS website along with specimen submittal forms at: http://chfs.ky.gov/dph/info/lab/

- Work with health departments to detect and monitor persons who have recently traveled to areas where the novel virus has been identified and who present with clinical illness consistent with influenza. Provide technical assistance and guidance to assess and report suspect cases of novel virus infection.

- Encourage all influenza sentinel providers to report data year-round and educate sentinel providers of enhanced surveillance activities, including submission of specimens to DLS, and of the need to report suspect cases to their local health department for further evaluation and testing.

- Recruit additional sentinel physicians to report ILI activity, collect respiratory specimens, and submit them for testing.

- Encourage reporting of all suspect human cases of the novel influenza virus cases of clinical illness consistent with a novel influenza virus through an electronic case reporting system.

- Generate daily reports of statewide influenza activity and distribute surveillance data to LHDs, regional epidemiologists, participating agencies, CDC, KDPH public information officers, and KY Emergency Management (KYEM).

- Review plans to further enhance influenza surveillance if efficient person-to-person transmission of the novel virus is confirmed, including training additional personnel on surveillance, case detection, contact tracing, and infection control issues.

- Work with the KDA, KY Poultry Federation (KPF), and KDFWR on enhanced surveillance and reporting of novel influenza virus detection in poultry workers, commercial and private poultry flocks, and in wild birds to identify disease activity in animal populations and to characterize the human threat.

- Collaborate with commercial laboratory stakeholders who are offering novel virus testing to report any preliminary positive results for novel virus infection to either the local health department or the DLS.

- Encourage submission of clinical specimens from ILI cases from all sources (public and private clinics, sentinel providers, and hospitals) and facilitate subtyping of influenza A viruses.

- In coordination with the CDC, develop, distribute and implement case management protocols to ensure that suspect human cases are promptly identified and isolated and that the source(s) of exposure (animal vs. human) are determined. Ensure protocols are distributed to LHDs and settings where cases and their contacts might be diagnosed.

- In collaboration with the CDC and LHDs, conduct, direct, coordinate, or provide guidance on epidemiologic investigations of human cases to identify the populations at risk, the current clinical characteristics of the disease, and the risk that infected persons or their environment may pose to others, including an assessment of likely human-to-human transmission.

- In conjunction with LHDs, develop a database or registry for case investigations, case management, case ascertainment, case reporting, surveillance, and data analysis.

- Coordinate with CDC and other partners on studies of viral shedding and determine the infectious and incubation periods for use in defining the duration of isolation and quarantine.

- Summarize and distribute study results to LHDs, and utilize the *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza*

Mitigation in the United States – Early, Targeted, Layered Use of Non-pharmaceutical Interventions to assess recommendations regarding the application and utility of non-pharmaceutical containment measures.

During WHO Pandemic Phase 5 (Pandemic Alert Period: Substantial pandemic risk with larger clusters of disease, but still limited human-to-human transmission; sustained community transmission possible), the DEHP will:

- Communicate with the CDC to monitor any changes in recommendations and guidelines for surveillance and diagnostic testing, including guidance on triaging specimens for testing and choosing which isolates to send the CDC and immediately inform LHDs and sentinel sites of new recommendations.

- Recommend which subset of suspect cases of ILI meet the criteria for influenza testing at either the institutional, local, or the state level and post recommendations on HAN and the KDPH Pandemic Influenza website: http://panflu.chfs.ky.gov

- Work closely with LHDs to manage new suspect cases, provide confirmatory testing, and implement containment strategies to prevent or limit local spread.

- Provide technical assistance to guide expanded testing on specific cases that represent a risk of spread of the novel virus infection in the community, including those who have an epidemiologic link to infected cases or who are hospitalized. Communicate with CDC concerning management, reference laboratory testing, and containment strategies in these cases.

- Continue working with the KDA, KPF, and KDFWR on enhanced surveillance and reporting of novel influenza virus detection in poultry workers, commercial and private poultry flocks, and in wild birds to identify disease activity in animal populations and to characterize the human threat.

- Communicate current surveillance criteria for cases of human novel virus infection, and the need to report data year-round and submit clinical specimens on ILI cases to sentinel providers and LHDs.

- Utilize WebEOC and EMSystems in conjunction with LHDs and hospitals to monitor bed counts and influenza and pneumonia-related hospitalizations and deaths.

- Generate daily reports of statewide influenza activity and make current surveillance data available to all participating agencies as well as the CDC, LHDs, regional epidemiologists, KDPH Public Information Officers, and KY EM.

- Maintain expanded critical laboratory testing capacity, including novel virus testing based on availability of reagents and laboratory supplies from manufacturers.

- Communicate via e-mail, Infection Control Listserv, HAN, WebEOC, *Kentucky Epidemiologic Notes and Reports*, and conference calls with stakeholders regarding the detection and circulation of novel virus worldwide and in the United States and provide detailed guidance on updated case definitions, diagnostic algorithms, laboratory infection control issues, surveillance criteria, case management, specimen collection, and appropriate testing.. As the pandemic progresses and guidelines and testing algorithms are revised, KDPH will communicate the changes and post the information on the KDPH Pandemic Influenza website at: http://panflu.chfs.ky.gov

- In coordination with the CDC, review and revise case management protocols to reflect current recommendations and epidemiologic data.

- Continue pandemic influenza-specific epidemiologic investigations and other special clinical studies.

B. Laboratory/ Epi Support for Seasonal Influenza Surveillance

- The DLS will ensure all participating sites will have a constant stock of test kits for rapid diagnosis based on the availability of reagents and supplies from manufacturers. The DLS monitors and replaces inventory weekly to ensure an abundant amount of supplies. During times of surge, inventory is monitored daily.

- The DEHP influenza coordinator will send guidelines to Local Health Department and Healthcare provider sentinel sites, and Local Health Department Surveillance Contacts, as well as health care providers who voluntarily submit specimens to the state laboratory, detailing routine surveillance guidelines recommended by the CDC and the WHO for submitting influenza isolates (i.e. numbers of samples, when to send samples etc.) See Appendix 1, 2, and 5.

- The DEHP will also send a reminder to those sites which request kits that the only portion of the kits which expire is the transport media. Staff at the sentinel site can order only this portion of a kit, if applicable.

- The DLS has implemented a plan for surveillance of ILI among laboratory personnel.

C. Laboratory/Epi Support for Novel Influenza Subtypes

In anticipation of pandemic influenza, the DLS has instituted several improvements in technology in preparation for surge capacity:

- DLS will use PCR typing for flu type A, B, H1, H3 and the H5 strains. This enables the detection of avian flu and identification of novel strains during routine surveillance.

- DLS will use R-mix shell vials, which allows for more rapid turn-around times. Incorporation of these technologies has decreased time for identification and typing of influenza from approximately 6 days to 2 days; however, this method has significantly increased the cost for reagents and kits for the identification and typing of influenza.

- DLS will use an ABI 7500 Fast PCR instrument to reduce turnaround time for influenza typing to 2 hrs (versus 4-5 hrs) once the virus is identified in culture.

- DLS will use an Easy Mag Extractor with capacity for high thru put extraction for influenza typing.

- Results are reported to healthcare submitters the same day they are confirmed and electronic reports are generated and submitted to the DEHP.

- DLS has purchased a PHIN compliant Lab Info System (LIMS) and has updated reporting procedures.

- DLS has provided collection instructions, shipping instructions, support for seasonal surveillance and novel strain typing as well as the influenza testing algorithms (See Appendices). This information is available to hospital and lab personnel statewide via the KDPH pandemic influenza website: http://panflu.chfs.ky.gov.

- DLS utilizes is the HAN which is available to healthcare providers, public health personnel, and KY Sentinel Labs throughout the state. HAN would be used as an early electronic warning system in the event of a pandemic.

- Current routine surveillance of influenza has allows DLS to monitor the referral of clinical samples from hospital labs, clinics and physician's offices by the use of sentinel sites for submission of samples for influenza analysis. These sentinel sites are located throughout KY to give a representative epidemiological view of influenza activity in the state and allow for year round surveillance of influenza.

- DLS monitors ILI among lab personnel and maintains a 24/7 call number accessible in the event of an after hours event. See Appendix 10.

- Through price contracts, standing orders, and procard purchases, the DLS has the capability to procure lab supplies, including collection kits, which would allow for a 100% increase in processing.

- In order to improve surge capacity, a local county health department laboratory (Louisville Metro Department of Health and Wellness) has been designated as an alternate site to perform novel flu testing if necessary. DLS is currently working with this site to provide training for their technologists as well as proficiency samples for quality assurance testing.

- DLS has an MOU with the 41st Civil Support Team of the National Guard. Their lab has PCR capabilities and is capable of performing novel flu testing.

- The Breathitt Veterinary Laboratory in Murray, KY can also be utilized if the DLS, Louisville Metro, and 41st Civil Support Team Laboratories, need additional laboratory capacity.

- The DLS will ensure all sentinel sites will have a constant stock of test kits for rapid diagnosis, based on availability from manufacturers. The DLS monitors and replaces inventory weekly to ensure an abundant amount of supplies. During times of surge, inventory is monitored daily.

- The state influenza coordinator will distribute the CDC guidelines for suspect avian flu cases (see Appendix 3, 4, and 5) to hospital infection control professionals, local influenza surveillance coordinators, LHDs and healthcare provider sentinel sites. In addition, "KDPH Guidelines for Reporting Suspected Cases of Avian Influenza" and instructions for submitting specimens will be posted on the KDPH Pandemic Influenza website: http://panflu.chfs.ky.gov, HAN, and published in the *Kentucky Epidemiologic Notes and Reports* publication.

- If ILI is suspected, a nasopharyngeal/throat specimen should be collected on viral media for transport. (Instructions for collection of these specimens are provided with the collection kits sent out by the DLS.) Concurrently, a rapid antigen test should be performed if ILI is suspected.

SEE APPENDIX 6 for DO's and DONT'S of specimen collection.

- If a specimen has been reported to contain influenza A virus (positive rapid antigen test) and the individual's condition meets the screening criteria (see Appendix 5) please contact the DEHP immediately to obtain a Screening Form. The DEHP will then determine if the CDC Director's Emergency Operations center should be contacted and fax the screening form if necessary.

- If a novel influenza subtype is confirmed through laboratory testing, the DEHP, specimen submitter, and LHD will be contacted immediately.

- In the event of a pandemic, submission of influenza samples may be restricted as determined by guidelines from CDC and the DEHP.

- The DEHP will develop extended addendum forms to the influenza screening form for tracking activities of suspected novel influenza cases (travel agenda, flight numbers, contacts…) similar to those used for SARS histories. (See Appendix 4.)

D. Laboratory Planning to Support the Response to a Pandemic

- For detection and characterization of novel influenza strains, PCR will be performed on any suspect avian or novel influenza strains. If needed, culture of these viruses will be performed only in the DLS BSL-3 Laboratory.

- The DLS has instituted year-round PCR typing for influenza type A, B, H1, H3, and H5 strains. This allows the capability to detect avian influenza as well as a novel strain during routine surveillance.

- The DLS has switched culture methods from traditional cell lines to R-mix shell vials. This has allowed for an overall decrease for identification and typing of influenza from approximately 6 days to 2 days.

- Laboratory reporting will be included in the testing algorithm and should be similar to the current standard.
    - Lab results can be reported electronically to LHDs.
    - Lab results can be reported via fax and de-identified results can be sent electronically via email.
    - Using the PHIN compliant Laboratory Information System (LIMS), laboratory results can be sent electronically to healthcare providers, LHDs, the CDC, and any entity submitting specimens for testing.

- Diagnostic reagents and kits will be distributed based upon their availability from manufacturers.

- Distribution of diagnostic reagents and test information for nursing homes to confirm influenza will be coordinated through the LHDs and the local health center nurses, and the DEHP influenza coordinator and the DLS.

- Distribution of diagnostic reagents and test information for sentinel sites will be coordinated through LHDs or sentinel labs, the DEHP influenza coordinator, and the DLS.

- Laboratory Surge Capacity Planning
    - DLS will continue cross-training of BT personnel in viral culture and PCR.
    - DLS will communicate and coordinate with DEHP to limit the number of samples submitted by any one site. This would also apply to the distribution of collection kits.
    - DLS will continue annual training, workshops, and monthly newsletters for the 65 sentinel laboratories throughout Kentucky. Each sentinel lab is registered in the KY HAN. Notification via HAN is exercised regularly. See Appendix 11 for a complete listing of all sentinel laboratories throughout Kentucky.
    - DLS will encourage the use of packaging and shipping certification training module for TRAIN.
    - DLS will provide influenza testing kits to sentinel sites, send additional rapid testing kits, assist them in screening samples, and conduct informational/training conference calls and teleconferences to improve surge capacity
    - DLS will continue working with the designated local health department laboratory for training and proficiency testing of technologists.
    - DLS will continue planning and coordination with the 41st Civil Support Team of the National Guard for laboratory capacity building.

- Local sentinel laboratories will utilize current packaging and shipping protocols for submitting specimens to DLS.

- The DLS will use established LRN protocols to submit specimens to the CDC.

- Partnerships
    - Healthcare providers and clinical labs
    - Packaging and shipping training provided by DLS.

IV. GUIDELINES FOR PANDEMIC PERIOD

Pandemic Surveillance Objectives

Case-based surveillance and control strategies should be maintained if it serves clear objectives, such as to support planning of the use of scarce resources, evaluate control measures or monitor changes in the influenza virus. The data collection process in this phase will be modified based on available resources.

At Phase 6 onset, case-based detection will be in place. During the peak of pandemic influenza activity, case-based detection methods will no longer be practical and surveillance data collection will be geared toward estimating community impact. Case-based detection will again become important as elimination of the pandemic influenza strain becomes feasible due to vaccine availability or an immune population.

Pandemic Influenza Virus Surveillance Activities (after case-based detection methods are no longer applicable)

Once a pandemic has been confirmed, monitor:

- Change in circulating virus, including development of anti-viral resistance, and shifts in the affected populations.
- Impact on human health, by conducting ongoing assessment of the morbidity and mortality.
- Evaluation of community- and population-based control measures, as applicable.

A. Epidemiological and Laboratory Surveillance for Human Infection

During WHO Pandemic Phase 6 (Pandemic Period: Increased and sustained transmission in the general population), the DEHP will:

- Monitor the epidemiology and impact of the pandemic on Kentucky.

- Communicate via e-mail, Infection Control Listserv, HAN, WebEOC, *Kentucky Epidemiologic Notes and Reports*, and conference calls with stakeholders regarding the detection and circulation of novel virus worldwide and in the United States and provide detailed guidance on updated case definitions, diagnostic algorithms, laboratory infection control issues, surveillance criteria, case management, specimen collection, and appropriate testing.. As the pandemic progresses and guidelines and testing algorithms are revised, KDPH will communicate the changes and post the information on the KDPH Pandemic Influenza website at: http://panflu.chfs.ky.gov
- Sustain the capacity to perform laboratory-based surveillance as long as possible because influenza viruses may undergo antigenic drift or develop resistance to antiviral drugs.

- Support LHDs, public and private medical providers, hospitals, and other stakeholders to maintain surveillance efforts for cases of novel virus infection. As the pandemic progresses and laboratory services become overwhelmed, public and private medical providers and hospitals may be asked to selectively submit clinical specimens as directed by the CDC. If laboratory supplies and reagents are exhausted, surveillance for novel virus infection will rely on a presumptive clinical diagnosis made by clinicians.

- Recommend discontinuing individual case reporting and request regular status reports from LHDs on cumulative statewide counts associated with novel virus infection, morbidity, and mortality. Such reports might include the number of:
    - Clinically suspected cases
    - Laboratory confirmed cases
    - Persons hospitalized with a novel virus infection
    - Deaths attributed to novel virus infection

- In collaboration with the CDC and LHDs, and as resources are available, conduct investigations to:
    - Describe unusual clinical syndromes
    - Describe unusual pathologic features associated with fatal cases
    - Determine efficacy of vaccination, if vaccine is available, or antiviral prophylaxis
    - Assess antiviral effectiveness in circulating strains to help refine antiviral recommendations and target high risk groups
    - Assess the effectiveness of non-pharmaceutical containment measures such as school and business closures

- Determine which populations are at greatest risk and, in conjunction with the CDC, refine and revise priority groups for vaccination as vaccine availability increases.

- Utilize the electronic death reporting system to track influenza and pneumonia-related deaths.

- Generate daily reports of statewide influenza activity and make current surveillance data available to all participating agencies as well as the CDC, LHDs, regional epidemiologists, KDPH Public Information Officers, and KYEM.

- As resources permit, and depending on guidance from the CDC, continue to conduct laboratory testing for influenza.

- As resources permit and as indicated by the CDC, characterize the strain of incoming specimens and isolates to detect antigenic drift variants and reassortant

viruses that could limit the efficacy of vaccines produced against the original pandemic strain.

- As resources permit, continue to perform laboratory testing critical to ongoing surveillance.

- Continue situation-specific pandemic influenza epidemiologic investigations and other special clinical studies, as necessary.

B. Laboratory Support for Disease Surveillance

- Support will remain the same as with routine surveillance. DLS will heighten communication with the DEHP.

- DLS will rely upon the CDC for recommendations in submission of samples, testing protocols and acquisition of reagents.

C. Laboratory Support for Clinicians

- The DEHP influenza coordinator will provide consultation to the local health department sentinel sites regarding when rapid detection kits should be used. DLS will provide rapid detection kit with instructions for collecting the specimens and performing the test as well as safe handling practices.

D. Biocontainment Procedures

- PCR may be performed in BSL-2. Viral culture must be performed in BSL-3.

E. Occupational Health Issues for Laboratory Workers

- If staffing becomes critically low due to illness or time off to care for family members, the DLS surge capacity plans of cross training will go into effect.

- DLS will provide all laboratory technicians education concerning the appropriate PPE, biosafety level techniques and preventive exposure precautions during the processing and testing of influenza as well as symptoms associated with ILI, and seasonal influenza vaccine for lab staff.

See HHS plan for appendix – guidelines for shipping as well as diagnostic assays.

Appendix 1

Influenza Sentinel Surveillance System (ISSS)

A. Sources of Information for the ISSS

Influenza like illness (ILI) is reported by sentinel Local Health Department (LHD) sites. All sites surveil absenteeism in a school district, or schools representative of grades K-12, for one day each week, with the exception of when school is not in session. Every site is requested to also surveil a nursing home for ILI. Some LHD sites also surveil health care providers and hospitals.

Sentinel Health Care Provider (HCP) sites report ILI to the Centers for Disease Control and Prevention (CDC), and obtain specimens for laboratory culture confirmation.

Mandatory reporting of culture confirmed cases within one week is required of laboratories.

Long-term care facilities are required by law to report immediately to the LHD, two or more ILI within a one-week period of time.

B. Description of Data Collected

Throughout the year, LHD sentinel sites send an email, fax, or phone in weekly reports of ILI counts received from medical practices, nursing homes, and hospitals; absenteeism for schools is collected on Tuesdays. Numbers and types of influenza virus isolates from clinical laboratories are maintained in a database and reported to CDC. HCP sentinel sites send information about ILI by age group to the CDC through an automated touch-tone system, fax or phone. The state influenza coordinator has access to the computer data. Laboratory confirmed cases, ILI reports from sentinel LHD sites and HCP sentinel sites are considered in determining the state's activity code for each week. The state's activity code is reported to the CDC. The information is also compared to previous weeks of the current season and to previous influenza seasons.

ILI cases and absentees for six weeks in the fall are used to determine outbreak baseline numbers for LHD sentinel site participants. HCPs and hospital outbreak baseline numbers are three ILI cases. The nursing home outbreak baseline number is two. School absentees for six weeks are added together, divided by six and multiplied by two to obtain an outbreak baseline number for each participating school district. Outbreak baseline numbers are used to compare the levels of ILI. The state influenza surveillance coordinator uses all the information to make a subjective determination regarding the influenza activity rating for the State Epidemiologist's report each week. Activity levels and definitions are:

- **No activity –** Overall clinical activity remains low and there are no lab confirmed cases
- **Sporadic –** Isolated cases of lab confirmed influenza in the state and ILI activity is not increased, or lab confirmed outbreak in a single institution in the state and ILI activity is not increased.
- **Local outbreak –** Increased ILI within a single region and recent (within the past three weeks) laboratory evidence of influenza in that region. ILI activity in other regions is not increased, or two or more institutional outbreaks (ILI or lab confirmed) within a single region and recent lab confirmed influenza in that region. Other regions do not have increased ILI and virus activity is no greater that sporadic in those regions.
- **Regional –** Increased ILI in greater than or equal to two but less than half of the regions and recent lab confirmed influenza in the affected regions, or institutional outbreaks (ILI or lab confirmed) in greater than or equal to two and less than half of the regions and recent lab confirmed influenza in the affected regions.
- **Widespread –** Increased ILI and/or institutional outbreaks (ILI or lab confirmed) in at least half of the regions and recent lab confirmed influenza in the affected regions and recent lab confirmed influenza in the state.

    - Lab confirmed case = case confirmed by rapid diagnostic test, antigen detection, culture, or PCR. (At the beginning of the season, the State Epidemiologist may report "No Activity" until there is evidence of culture confirmed cases in the state regardless of rapid antigen reports.)
    - Institution includes nursing home, hospital, prison, school, etc. ILI activity can be assessed using a variety of data sources including sentinel providers, school/workplace absenteeism, and other syndromic surveillance systems that monitor ILI.
    - Region-Geographical subdivision of a state defined by the Department for Public Health (DPH). In KY, the 15 Area Development Districts (ADDs) are used. The identity of specific isolates from Kentucky and other nearby states, and information on the age of the person tested and date of collection of the isolate, are used to interpret whether outbreaks of ILI in the state actually represent influenza, and if so, what type and whether the strain is thought to be a close match to the content of the currently available vaccine.

C. Data Publications

Data publications include *Kentucky Epidemiologic Notes and Reports* seasonal summary, weekly influenza laboratory confirmed cases charts on the website: http://panflu.chfs.ky.gov, *Yearly Reportable Disease Summary*, and the *Five-year Summary for Reportable Diseases*.

D. Data Limitations

The system relies on the accuracy of reporting by the sentinel sites.

E. Uses of Information

The activity information can be used to promote influenza immunization, let clinicians know whether the circulating strain is a match for the current vaccine; and whether it is one which will respond to antiviral chemoprophylaxis and therapy. In addition, laboratory information can be used to prepare for responding to an influenza pandemic. The public can be informed about what influenza strain is circulating, how influenza activity compares with other years, and what populations are affected. The state influenza coordinator sends a weekly activity report to the Cabinet's Communications Office and the CHR Infection Control listserv for release to the media.

F. System Evaluation

The system is informally evaluated in May of each year. Summary information is evaluated by the state influenza surveillance coordinator, and the coordinator determines how well the system provided answers to the frequently asked questions during the season. The system has not been formally evaluated.

Appendix 2

GUIDELINES FOR SUBMITTING INFLUENZA VIRUS ISOLATES TO THE WHO COLLABORATING CENTER FOR INFLUENZA, CDC 2005-06 SEASON

The use of rapid antigen detection methods for influenza is increasing and provides valuable information for clinicians. However, we would like to stress the importance of continuing virus isolation. The antigenic analysis of circulating strains of influenza, which is dependent upon the isolation of influenza virus, is necessary for the successful selection of each year's influenza vaccine strains. We appreciate your contributions in this critical public health effort by submitting influenza isolates for antigenic analysis. Influenza isolates of particular importance for antigenic analysis are listed below.

1. **Pre-season isolates** from persons whose influenza illness appears related to overseas travel and the first isolates of the season. These isolates can provide important information regarding the match between vaccine and circulating strains for the current year and provide information necessary for vaccine formulation for the next year. Imported cases of influenza A that cannot be subtyped may also be indicative of an imported avian influenza human infection.
2. **Isolates collected during the beginning of increased influenza activity** (usually during December and early January) and during peak activity (usually mid-January to early February). Five isolates from each time period are requested.
3. **Late season isolates**, after major outbreak activity is over. These isolates may be the harbingers of new variants that are just beginning to circulate.
4. **Isolates of a type or subtype present as a minor component** (10% or less) of the year's epidemic.
5. **Isolates that cannot be subtyped by HI testing with kit reagents.** Please telephone (404) 639-3591. Isolates of influenza A that cannot be subtyped could be indicative of avian influenza. It is important to contact the state health office and send the specimen or isolate to the CDC Influenza Laboratory.
6. **Isolates from persons receiving an antiviral agent or from their contacts who become ill.** The increased use of antiviral agents for treatment and prophylaxis of influenza has created the potential for the emergence and spread of antiviral resistant viruses.
7. **Isolates from persons who are immunized against influenza**, for example, in nursing homes where residents were immunized with the current vaccine.
8. **Isolates from cases of suspected animal-to-human transmission** of influenza virus. These are needed to monitor the characteristics of the viruses and to examine the potential for spread.

B. See attachment- Human influenza A (H5) domestic case screening form and instructions.

C. See attachement -Reporting suspected avian flu cases and collection guidelines.

C. Laboratory Algorithm for flu testing and reporting

Influenza Testing Algorithm

Tube Culture Influenza Isolation & Identification

Specimen Collection

Step 1 Isolation swabs collection kits are provided by the DLS to sentinel Influenza sites, Health Depts, Hospitals, Health Care Clinics, and Doctor's Offices. These kits contain all the materials and Instructions for collecting and submitting flu samples to the DLS.

Step 2 The preferred submissions are Nasal or Throat swabs that are collected and shipped overnight in the M4RT transport media provided in the kit.

Step 3 Prepaid mailing labels are provided with the isolation kits to facilitate their shipment.

Day One at the DLS

Step 1 Specimen Receipt

Step 2 Log In

Step 3 Swab Preparation

Step 4 Inoculation - Tube Culture Lines

Note* - Any specimen received that meets the case definition or is highly suspected of being a possible novel (example A-H5N1) flu strain is immediately pulled for PCR flu testing to facilitate faster identification of its strain type.

Day Two - Day Nine

Daily Tube Readings

Step 1 The tube lines are read using a light microscope for signs of CPE. (Cytopathic effect)

Step 2 If positive CPE is observed then the specimen tubes are pulled for Resp IFA testing.

Step 3 If the Resp IFA shows Pos for Flu A or B then a culture tube of primary Monkey or Canine Kidney is pulled for the Hemaglutination test (HA).

Step 4 At various days of Incubation (usually 3 to 6 days) primary Monkey or Canine Kidney tubes are pulled for the HA test and performed, regardless of the presence of Positive CPE.

Step 5 Any specimen testing positive for the HA test is considered tittered for the Hemaglutination Inhibition test (HI) to obtain flu strain typing. A positive HA test is necessary before an HI can be performed.

Step 6 A HI test is performed on all positive HA specimens and will be identified as a flu strain type (A H3N2, A H1N1, or a B type).

Step 7 Any specimen testing IFA pos for FLU A or HA positive that is not identified by the HI test is considered an aberrant sample and immediately sent to CDC for strain typing confirmation.

Step 8 Any specimen deemed aberrant is then tested by the PCR flu test to identify any possible Flu A H5N1 activity.

Step 9 Samples testing positive and identified by HI and/or PCR are resulted immediately to submitter and epidemiology.

Step 10 At the end of Nine days of observation any specimen that shows no signs of CPE, has tested Neg by Resp IFA, and is HA negative is resulted as "NO VIRUS ISOLATED".

Human Influenza A (H5) Domestic Case Screening Form

CDC Case ID:

1. Reported By

Date reported to state or local health department: __ __ / __ __ / __ __ __ __ (m m d d y y y y)	State/ local Assigned Case ID:
Last Name:	First Name:

State:	Affiliation:	Email:
Phone 1:	Phone 2:	Fax:

2. Patient Information

City of Residence: County: State:

Age at onset: _____ ☐ Year(s) ☐ Month(s)

Sex: ☐ Male ☐ Female

Race: *(Choose One)*
☐ American Indian/Alaska Native ☐ White
☐ Asian ☐ Unknown
☐ Black
☐ Native Hawaiian/Other Pacific Islander

Ethnicity: ☐ Non Hispanic ☐ Hispanic

3. Optional Patient Information

Last Name: First Name:

4. Signs and Symptoms

A. Date of symptom onset: __ __ / __ __ / __ __ __ __ (m m d d y y y y)

B. What symptoms and signs did the patient have during the course of illness? (check all that apply)

Fever > 38° C (100.4° F)	Feverish (temperature not taken)	Conjunctivitis
Cough	Headache	Shortness of breath
Sore throat	Other (specify): _____	

C. Was a chest X-ray or chest CAT scan performed? ☐ Yes* ☐ No ☐ Unknown

If yes*, did the patient have radiographic evidence of pneumonia or respiratory distress syndrome (RDS)? ☐ Yes* ☐ No ☐ Unknown

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CENTERS FOR DISEASE CONTROL AND PREVENTION
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Epidemiologic Risk Factors

CDC Case ID:

5. Travel/Exposures

A. In the 10 days prior to illness onset, did the patient travel to any of the countries listed in the table below? If yes*, please fill in arrival and departure dates for all countries that apply. ☐ Yes* ☐ No** ☐ Unknown

****If patient did not travel outside U.S., skip to question 6.**

Country	Arrival Date	Departure Date	Country	Arrival Date	Departure Date
☐ Afghanistan			☐ Myanmar (Burma)		
☐ Bangladesh			☐ Nepal		
☐ Brunei			☐ North Korea		
☐ Cambodia			☐ Oman		
☐ China			☐ Pakistan		
☐ Hong Kong			☐ Papua New Guinea		
☐ India			☐ Philippines		
☐ Indonesia			☐ Saudi Arabia		
☐ Iran			☐ Singapore		
☐ Iraq			☐ South Korea		
☐ Israel			☐ Syria		
☐ Japan			☐ Taiwan		
☐ Jordan			☐ Thailand		
☐ Laos			☐ Turkey		
☐ Lebanon			☐ Viet Nam		
☐ Macao			☐ Yemen		
☐ Malaysia					

For the questions 5B to 5E,
In the 10 days prior to illness onset, <u>while in the countries</u> listed above . . . .

B. Did the patient come within 1 meter (3 feet) of any live poultry or domesticated birds (e.g. visited a poultry farm, a household raising poultry, or a bird market)? ☐ Yes* ☐ No ☐ Unknown

If Yes*

C. Did patient touch any recently butchered poultry? ☐ Yes ☐ No ☐ Unknown

D. Did the patient visit or stay in the same household with anyone with pneumonia or severe flu-like illness? ☐ Yes ☐ No ☐ Unknown

E. Did the patient visit or stay in the same household with a suspected human influenza A(H5) case?* ☐ Yes ☐ No ☐ Unknown

F. Did the patient visit or stay in the same household with a known human influenza A(H5) case?* ☐ Yes ☐ No ☐ Unknown

** SEE Influenza A (H5): Interim U.S. Case Definitions*

(continued from previous page)

CDC ID:

6. Exposure for Non Travelers	
For patients whom did not travel outside the U.S., **in the 10 days prior to illness onset**, did the patient visit or stay in the same household with a traveler returning from one of the countries listed above who developed pneumonia or severe flu-like illness?	☐ Yes* ☐ No ☐ Unknown
If yes*, was the contact a confirmed or suspected H5 case patient?	☐ Yes* ☐ No ☐ Unknown
If yes*: CDC ID: _____ STATE ID: _____	

Laboratory Evaluation

7. State and local level influenza test results	
Specimen 1	
☐ NP swab ☐ Broncheoalveolar lavage specimen (BAL) ☐ NP aspirate ☐ OP swab ☐ Other _____	Date Collected: __ __ / __ __ / __ __ __ __ m m d d y y y y
Test Type: ☐ RT-PCR ☐ Direct fluorescent antibody (DFA) ☐ Viral Culture ☐ Rapid Antigen Test* *Name of Rapid Test:	Result: ☐ Influenza A ☐ Influenza B ☐ Influenza (type unk) ☐ Negative ☐ Pending
Specimen 2	
☐ NP swab ☐ Broncheoalveolar lavage specimen (BAL) ☐ NP aspirate ☐ OP swab ☐ Other _____	Date Collected: __ __ / __ __ / __ __ __ __ m m d d y y y y
Test Type: ☐ RT-PCR ☐ Direct fluorescent antibody (DFA) ☐ Viral Culture ☐ Rapid Antigen Test* *Name of Rapid Test:	Result: ☐ Influenza A ☐ Influenza B ☐ Influenza (type unk) ☐ Negative ☐ Pending
Specimen 3	
☐ NP swab ☐ Broncheoalveolar lavage specimen (BAL) ☐ NP aspirate ☐ OP swab ☐ Other _____	Date Collected: __ __ / __ __ / __ __ __ __ m m d d y y y y
Test Type: ☐ RT-PCR ☐ Direct fluorescent antibody (DFA) ☐ Viral Culture ☐ Rapid Antigen Test* *Name of Rapid Test:	Result: ☐ Influenza A ☐ Influenza B ☐ Influenza (type unk) ☐ Negative ☐ Pending

(continued from previous page)

CDC ID:

8. List specimens sent to the CDC

Select a SOURCE* from the following list for each specimen: Serum (acute), serum (convalescent), NP swab, NP aspirate, broncheoalveolar lavage specimen (BAL), OP swab, tracheal aspirate, or tissue

Specimen 1: ☐ Clinical Material ☐ Extracted RNA ☐ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ (m m d d y y y y) Date Sent: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
Specimen 2: ☐ Clinical Material ☐ Extracted RNA ☐ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ (m m d d y y y y) Date Sent: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
Specimen 3: ☐ Clinical Material ☐ Extracted RNA ☐ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ (m m d d y y y y) Date Sent: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
Specimen 4: ☐ Clinical Material ☐ Extracted RNA ☐ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ (m m d d y y y y) Date Sent: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
Specimen 5: ☐ Clinical Material ☐ Extracted RNA ☐ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ (m m d d y y y y) Date Sent: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
Carrier:	Tracking #:	

9. Case Notes:

(continued from previous page)

CDC ID:

CDC Contact Information (FOR CDC USE ONLY)	
Case status and date status applied: □ Clinical Case (lab results pending) __ __ / __ __ / __ __ __ __ (m m d d y y y y) □ Influenza A pos. Case (subtype pending) __ __ / __ __ / __ __ __ __ (m m d d y y y y) □ Confirmed Case __ __ / __ __ / __ __ __ __ (m m d d y y y y)	□ Ruled Out/Non-Case: __ __ / __ __ / __ __ __ __ (m m d d y y y y) Reason: □ Influenza A neg. (by PCR, viral culture, or influenza A serology) □ Non-H5 Influenza Strain □ Other etiology* □ Did not meet case definition
Date Entered by CDC: __ __ / __ __ / __ __ __ __ (m m d d y y y y)	Contact Date: __ __ / __ __ / __ __ _ __ (m m d d y y y y)
Name of CDC Contact:	

*Alternative Diagnosis			
A. Was an alternative non-influenza respiratory pathogen detected? If yes* specify:	□ Yes*	□ No	□ Unknown
B. Was there a diagnosis other than respiratory infection? If yes* specify:	□ Yes*	□ No	□ Unknown

Influenza A (H5) Domestic Case Screening Form Instructions

Q1. Reported By

Date reported to state or local health department: Date case was first reported to the state or local health department.

State/local Case ID: Case number used by local jurisdiction to identify case.

Last name, First name, State, Affiliation, Email, Phone 1, Phone 2, Fax: Information on how to contact the state or local official responsible for following case.

Q2. Patient Information

HIPPA Note: Please note that CDC is conducting these activities in its capacity as a public health authority, as defined by the Health Insurance Portability and Accountability Act (HIPAA). Health care providers and health departments **may therefore disclose protected health information to CDC** without individual authorization. The information being requested represents the minimum necessary to carry out the public health purposes of this project pursuant to 45 CFR §164.514(d) of the Privacy Rule, and protected health information will not be disseminated. Nevertheless, individual local and state health department privacy policies may vary, and should be followed accordingly.

Age at onset: If patient less than one month old, round age up to one month.

Race: Please choose only one race. For multiracial patients indicate race they most closely identify with.

Ethnicity: Please answer this question **in addition** to the Race question above.

Q3. Optional Patient Information

Last name, First name: Please see HIPAA note above. The patient's initials should be listed if state or local policies preclude release of the patient's name.

Q4. Signs and Symptoms – Self-explanatory

Q5. Travel/Exposure

Q5A: The list of affected countries may change. CDC will notify state and local health officials if the list of affected countries changes. In addition, a current list of affected Asian countries can be found at the World Organization for Animal Health website (http://www.oie.int/downld/AVIAN INFLUENZA/A_AI-Asia.htm).

Transit through an airport (i.e., patient did not leave the airport) within an affected country **does not** count as exposure in that country. If patient **did not** travel to any countries affected by

avian influenza outbreaks within 10 days prior to illness onset, skip to Question 6 on Exposure for Non-Travelers.

Q5E: Clinical and epidemiologic criteria for a suspect case in an affected country:

Any person with radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS), or other severe respiratory illness (regardless of poultry exposure)

OR

Any person with **all** of the following:

1) documented temperature of >100.4°F (>38°C), **and**;
2) cough, sore throat, or shortness of breath; **and;**
3) history of contact with
    a. poultry or domestic birds (e.g., visited a poultry farm, a household raising poultry, or a bird market) **or**
    b. Anyone hospitalized or died of a flu-like illness.

Q6. Exposure for Non-Travelers: See clinical and epidemiologic criteria for influenza A(H5) above

Q7. State and local level influenza testing section – Check off type of specimen, date of specimen collection, type of testing and results for tests conducted at the state and/or local level.

Q8. List Specimens sent to the CDC – Check type(s) of specimen being sent (i.e, clinical material, extracted RNA, or viral isolate).

List specimen source (i.e., Serum (acute), serum (convalescent), nasopharyngeal (NP) swab or aspirate, broncheoalveolar lavage specimen (BAL), oropharyngeal (OP) swab, tracheal aspirate, or tissue (specify source)), and dates collected and sent.

Note: Please list acute and convalescent sera as separate specimens.

Q9. Case Notes: Please include in notes section any pertinent information not covered in the questionnaire.

CDC Contact Information Section – For CDC use only

CDC Case ID: CDC case ID number will be automatically generated when initiating new data entry form. The number system for cases identified in the United States will start with USH5 and the two-digit year, followed by a dash and the two letter state code for the state where the case was identified and a 4 digit sequential number starting with 0501 (e.g., the first surveillance case identified in 2005 in Alabama would have CDC case ID USH505-AL0501).

Clinical case: Indicates the patient meets the influenza A(H5) surveillance clinical criteria (see box below). Include date patient met clinical case definition

Influenza A positive case: Indicates the patient meets the influenza A(H5) surveillance criteria (see box below) and has a positive influenza A test at the state or local level. Include date of positive influenza A test.

Confirmed Case: Indicates the patient meets the influenza A(H5) surveillance criteria and has a positive influenza A(H5) test confirmed by the CDC Influenza Lab (see box below). Include date of positive influenza A(H5) test.

Ruled out/Non-case: Indicates that the patient had a negative PCR or culture for influenza A, had known non-H5 human influenza (i.e., influenza A(H1), influenza A(H3), or influenza B), had an alternative diagnosis other than human influenza, or did not meet influenza A(H5) clinical or epidemiologic criteria for a suspect case. (see box below).

Date Entered by CDC: Date data is entered into CDC database

CDC Contact: Name of CDC personnel responsible for following case

Contact Date: Date case was first reported to the CDC

Influenza A (H5) Surveillance Criteria

1. Patient is hospitalized and has:
    a. radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS), or other severe respiratory illness for which an alternative diagnosis has not been established **and;**
    b. a history of travel within 10 days of symptom onset to a country with documented H5N1 avian influenza infections in poultry or humans. Ongoing listings of Asian countries affected by avian influenza are available from the World Organization for Animal Health (http://www.oie.int/downld/AVIAN INFLUENZA/A_AI-Asia.htm).

OR

2. Patient is hospitalized or ambulatory and has:
    a. documented temperature of >100.4°F (>38°C), **and**;
    b. cough, sore throat, or shortness of breath; **and either;**
    c. history of contact within 10 days prior to onset of symptoms with:
        i. poultry or domestic birds (e.g., visited a poultry farm, a household raising poultry, or a bird market) in an affected country **or**
        ii. a patient with known or suspected influenza A(H5) infection.

    OR

    d. traveled to an affected country within 10 days prior to onset of symptoms and tests positive for influenza A

Confirmed influenza A(H5) case

Patient is suspect case of influenza A(H5N1) and is laboratory confirmed by CDC as influenza A(H5) positive by:

a. PCR, or
b. viral culture, or
c. influenza A(H5) specific serology

Guidelines for reporting domestic suspect and confirmed human cases of avian influenza A(H5) to CDC and the collection and shipping of specimens for influenza A(H5) testing

Since February 3, 2004, CDC has issued several Health Alert updates requesting that local and state health departments enhance surveillance for human avian influenza A (H5) illnesses. The following document contains more detailed information on reporting and on the collection, shipping and testing of clinical specimens. A case report form and instructions are also attached.

In collaboration with state and local health departments, CDC is collecting information on suspect and confirmed human influenza A(H5) cases in the United States. This effort is intended to enhance current influenza surveillance for early identification of patients with influenza A(H5) infection. CDC requests that state and local health departments obtain specimens for influenza virus testing on patients meeting the influenza A (H5) surveillance criteria below.

Influenza A (H5) Surveillance Criteria

1. Patient is hospitalized and has:
    a. radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS), or other severe respiratory illness for which an alternative diagnosis has not been established **and;**
    b. a history of travel within 10 days of symptom onset to a country with documented H5N1 avian influenza infections in poultry or humans. Ongoing listings of Asian countries affected by avian influenza are available from the World Organization for Animal Health (http://www.oie.int/downld/AVIAN INFLUENZA/A_AI-Asia.htm).

OR

2. Patient is hospitalized or ambulatory and has:
    a. documented temperature of >100.4°F (>38°C), **and**;
    b. cough, sore throat, or shortness of breath; **and either;**
    c. history of contact within 10 days prior to onset of symptoms with:
        i. poultry or domestic birds (e.g., visited a poultry farm, a household raising poultry, or a bird market) in an affected country **or**
        ii. a patient with known or suspected influenza A(H5) infection.

Patients meeting the influenza A (H5) surveillance criteria may be tested at the state/local level for influenza A or influenza A(H5) if laboratory capacity is available. **See Laboratory Testing Procedures section below for precautions on working with clinical specimens that potentially contain influenza A(H5).**

Specimens from persons meeting the influenza A (H5) surveillance criteria should be sent to the CDC if:

1. specific influenza A(H5) testing done at the state /local laboratory is positive **(this should be done only if the laboratory is able to test for influenza A(H5) by PCR or if they have a BSL 3 with enhancements facility for influenza A(H5) viral culture)**,

OR

2. testing for influenza A is positive by PRC or rapid antigen detection* and the referring jurisdiction is not equipped to test for influenza A(H5),

OR

3. the referring jurisdiction is not equipped to test for influenza A by PCR and is requesting testing at CDC.

State and local health departments **should not** report patients who meet the clinical and epidemiologic criteria but who have an alternative laboratory confirmed diagnosis (e.g. influenza A(H3), influenza A(H1), influenza B, or a non-influenza etiology) or who have tested negative for influenza A by PCR.

*Because the sensitivity of commercially available rapid diagnostic tests for influenza may not always be optimal, CDC also will accept specimens from persons meeting the above clinical criteria even if they test negative by influenza rapid diagnostic testing if PCR assays are not available at the state laboratory.

A **confirmed human influenza A(H5) case** is a case meeting surveillance criteria above that is laboratory confirmed by CDC as influenza A(H5) positive by:

a. PCR, or
b. viral culture, or
c. influenza A(H5) specific serology

HIPAA

CDC is conducting these activities in its capacity as a public health authority, as defined by the Health Insurance Portability and Accountability Act (HIPAA). Health care providers and health departments **may therefore disclose protected health information to CDC** without individual authorization. The information being requested represents the minimum necessary to carry out the public health purposes of this project pursuant to 45 CFR §164.514(d) of the Privacy Rule, and protected health

information will not be disseminated. Nevertheless, individual local and state health department privacy policies may vary, and should be followed accordingly.

Reporting Suspect Cases of Human Influenza A(H5)

A. Initial Report: Prior to submitting a case report form, health department officials should first contact the CDC Director's Emergency Operations Center (DEOC) at 770-488-7100. This number is available 24 hours a day, 7 days a week. DEOC staff will notify a member of the human influenza A(H5) surveillance team who will contact the health department and provide a unique CDC case ID number for each case which meets the surveillance criteria.

B. Written Materials

1. **Case Report Form:** Following the initial telephone report, health department officials should submit a completed CDC case report form. This form is available through Epi-X, or by contacting CDC DEOC at 770-488-7100.
2. **Sending case report form to CDC:** Materials should be faxed to CDC at 888-232-1322. Please include the CDC case ID number, contact information, and a cover sheet with the header "ATTN: Influenza A(H5N1) case reporting." Rapid return of information is of high priority; complete as much of the case report form as possible and transmit to CDC within 3 to 5 business days of first contact. The remaining information can be sent as soon as it is available. CDC staff will assist local and state health departments in completing the case report forms as needed.

C. Laboratory Procedures, Specimen Collection and Shipment

1. **Laboratory precautions for influenza A (H5) testing:** Highly pathogenic avian influenza A(H5N1) is classified as a select agent and **must be** worked with under Biosafety Level (BSL) 3+ laboratory conditions.
    a. **Culture only at BSL 3 with enhancements level facilities.** This includes controlled access double door entry with change room and shower, use of respirators, decontamination of all wastes, and showering out of all personnel. Laboratories working on these viruses must be certified by the U.S. Department of Agriculture. CDC does **not recommend** that virus isolation studies on respiratory specimens from patients who meet the above criteria be conducted unless stringent BSL 3 with enhancements conditions can be met and work is separate from other human influenza A (i.e., H1 or H3) virus work. Therefore, respiratory virus cultures should not be performed in most clinical laboratories and cultures should not be ordered for patients suspected of having influenza A (H5N1) infection.

b. **PCR and rapid antigen detection:** Clinical specimens from suspect influenza A(H5) cases may be tested at the state/local public health laboratory by PCR assays using standard BSL 2 work practices in a Class II biological safety cabinet. In addition, commercial rapid antigen detection testing can be conducted under BSL 2 levels to test for influenza.

2. To assist public health public health laboratories respiratory illness diagnostic efforts, CDC has developed real-time PCR protocols for a number of respiratory pathogens, including influenza A and B viruses, adenovirus, metapneumovirus, Legionella, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae*. **These protocols are currently available only to public health laboratories and have been posted at the APHL Members Only (password required) Web site** www.aphl.org/Members_Only/index.cfm, under SARS. These protocols are not available in all public health laboratories, and physicians should consult with their local public health laboratory when ordering these tests.

3. **Sample Collection and Shipping instructions**
   a. **Respiratory specimens:** Aliquots of extracted RNA (for PCR positives) and/or clinical specimen (i.e., nasopharyngeal and oropharyngeal swabs, nasal washings, tracheal aspirates) should be sent through established channels (e.g., via the state laboratory) or directly to CDC for viral characterization.

      Specimens should be frozen at -70^{o} C and shipped on **dry ice** directly to CDC **overnight** to the address in Section 4d.

   b. **Serum specimens:** A serum sample (5-10 cc) should be collected in a serum separator tube, centrifuged, and stored locally at -20^{o} F. A convalescent serum sample should be drawn 2-4 weeks later and both acute and convalescent sera should be sent to the CDC for serologic testing.

   c. **Autopsy Specimens:** CDC can perform immunohistochemical (IHC) staining for influenza A(H5) viruses on autopsy specimens. Viral antigens may be focal and sparsely distributed in patients with influenza, and are most frequently detected in respiratory epithelium of large airways. Larger airways (*particularly primary and segmental bronchi*) have the highest yield for detection of influenza viruses by IHC staining. Collection of the appropriate tissues ensures the best chance of detecting the virus by (IHC) stains. If influenza is suspected, a minimum total of 8 blocks or fixed tissue specimens representing samples from each of the following sites should be obtained and submitted for evaluation:

1. Central (hilar) lung with segmental bronchi
2. Right and left primary bronchi
3. Trachea (proximal and distal)
4. Representative pulmonary parenchyma from right and left lung

In addition, representative tissues from major organs should be submitted for evaluation. In particular, for patients with suspected myocarditis or encephalitis, specimens should include myocardium (right and left ventricle) and CNS (cerebral cortex, basal ganglia, pons, medulla, and cerebellum). Specimens should be included from any other organ showing significant gross or microscopic pathology.

Specimens may be submitted as:

1. Fixed, unprocessed tissue in 10% neutral buffered formalin, or
2. Tissue blocks containing formalin-fixed, paraffin-embedded specimens, or
3. Unstained sections cut at 3 microns placed on charged glass slides (10 slides per specimens)

Specimens should be sent at room temperature (**NOT FROZEN**)

Please include a copy of the autopsy report (preliminary or final if available), and a cover letter outlining a brief clinical history and the full name, title, complete mailing address, phone, and fax numbers of the submitter, in the event that CDC pathologists require further information. Referring pathologists may direct specific questions to CDC pathologists.

4. Shipping Instructions:

a. Specimens should be submitted to CDC by state and local health departments. The Influenza A(H5) Epi/Surveillance Team should be contacted at 770-488-7100 before sending specimens for influenza A(H5) testing.

b. When sending clinical specimens, please include the **specimen inventory sheet (appendix A)**, include the assigned **CDC case ID number,** and indicate **"Human Influenza A(H5) surveillance"** on all materials and specimens sent.

c. Please include the **CDC case ID number** on all materials forwarded to CDC. Protocols for standard interstate shipment of etiologic agents should be followed, and are available at http://www.cdc.gov/od/ohs/biosfty/shipregs.htm.

d. Address for respiratory and serum specimens:

Dr. Alexander Klimov, PhD, ScD, Chief
Strain Surveillance Section
Influenza Branch, CDC
c/o DASH
1600 Clifton Road
Atlanta, GA 30333
Phone: 404-639-3387 or 3591, fax: 404-639-2334, email: AKlimov@cdc.gov

Address for autopsy specimens

Dr. Sherif Zaki, MD, PhD
Infectious Disease Pathology Activity
Division of Viral and Rickettsial Diseases
National Center for Infectious Diseases
Centers for Disease Control and Prevention
Mailstop G-32, Bldg 1, Rm 2301
1600 Clifton Road
Atlanta, GA 30333
Phone: 404-639-3133
fax: 404-639-3043
email: SZaki@cdc.gov

5. ADDITIONAL INFORMATION

Any questions regarding reporting procedures or specimen shipment can be directed to the influenza special investigations team:

Influenza A(H5N1) Epi/Surveillance Team
Division of Viral and Rickettsial Diseases
National Center for Infectious Diseases
Centers for Disease Control and Prevention
Mailstop A-32, Bldg 6, Rm 122
1600 Clifton Road
Atlanta, GA 30333
Phone: 770-488-7100, Fax: 888-232-1322
Email: eocinfluenza@cdc.gov

PHONE NUMBERS

Reporting cases and Notification of specimen shipments	770-488-7100
Fax number for case report forms	888-232-1322
Requests for specimen testing	770-488-7100
Dr. Alexander Klimov, Strain Surveillance	404-639-3387
Dr. Sherif Zaki, Infectious Disease Pathology	404-639-3133

Appendix A

CDC CASE ID:

List specimens sent to the CDC		
Select a SOURCE* from the following list for each specimen: Serum (acute), serum (convalescent), NP swab, NP aspirate, broncheoalveolar lavage specimen (BAL), OP swab, tracheal aspirate, or tissue		
Specimen Type #1: □ Clinical Material □ Extracted RNA □ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ (m m d d y y y y) Date Sent: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
Specimen Type #2: □ Clinical Material □ Extracted RNA □ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ (m m d d y y y y) Date Sent: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
Specimen Type #3: □ Clinical Material □ Extracted RNA □ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ (m m d d y y y y) Date Sent: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
Specimen Type #4: □ Clinical Material □ Extracted RNA □ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ (m m d d y y y y) Date Sent: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
Specimen Type #5: □ Clinical Material □ Extracted RNA □ Virus Isolate	Source*: _____	Collected : __ __ / __ __ / __ __ __ __ (m m d d y y y y) Date Sent: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
Carrier:	Tracking #:	

Appendix 6

Specimen Collection Guidelines For Influenza Specimens

1. Do collect a throat or nasopharyngeal swab.

2. Do use collection kits provided by the Division of Laboratory Services (M4RT media and Dacron swabs)
   - Also acceptable are kits specified for viral transport. Follow guidelines suggested by the manufacturer for storage of media.
   - M4RT media is stored at room temperature until use

3. Once specimen is collected it should be refrigerated.

4. Ship specimen with ice packs and in accordance with your facilities policies (Specimen may be shipped diagnostic).

5. Submit with Viral isolation form 275. If you do not have this form you may call (502) 564-4446 and one will be faxed to you.

THINGS TO AVOID when submitting Influenza specimens:

DO NOT submit in saline

DO NOT submit using cotton swabs or swabs with wooden shafts

DO NOT submit nasal aspirates

DO NOT submit specimens at room temperature

NOTE: Specimens may be submitted on dry ice but it is not necessary.

Instructions for Collecting and Packaging Influenza Specimens

Collection Guidelines

1. Use only sterile dacron or rayon swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden sticks, as they may contain substances that inactivate some viruses and inhibit PCR testing.

2. Use kits supplied by the Division of Laboratory Services.
   - -Kits specified for viral transport are also acceptable. Follow manufacture's guidelines for storage of media.
   - -M4RT media supplied by DLS is stored at room temperature until use.

3. Collect a nasopharyngeal swab.
   a. To obtain a nasopharyngeal swab, insert a swab into the nostril parallel to the palate.
   b. Leave the swab in place for a few seconds to absorb secretions.

4. Once specimen is collected it should be refrigerated.

Safety Precautions

http://www.cdc.gov/flu/professionals/infectioncontrol/healthcarefacilities.htm
http://www.cdc.gov/flu/avian/professional/infect-control.htm

Seasonal Influenza

Standard Precautions plus Droplet Precautions are recommended for the care of patients infected with human influenza.

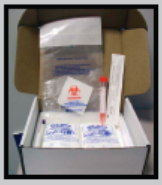
Avian Influenza

Standard Precautions
- -Pay careful attention to hand hygiene before and after all patient contact or contact with items potentially contaminated with respiratory secretions.

Contact Precautions
- -Use gloves and gown for all patient contact.
- -Use dedicated equipment such as stethoscopes, disposable blood pressure cuffs, disposable thermometers, etc.
- -Eye protection (i.e., goggles or face shields)
- -Wear when within 3 feet of the patient.

Airborne Precautions
- -Place the patient in an airborne isolation room (AIR). Such rooms should have monitored negative air pressure in relation to corridor, with 6 to 12 air changes per hour (ACH), and exhaust air directly outside or have recirculated air filtered by a high efficiency particulate air (HEPA) filter. If an AIR is unavailable, contact the health-care facility engineer to assist or use portable HEPA filters (see Environmental Infection Control Guidelines) to augment the number of ACH.
- -Use a fit-tested respirator, at least as protective as a National Institute of Occupational Safety and Health (NIOSH)-approved N-95 filtering facepiece (i.e., disposable) respirator, when entering the room.

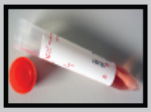
Packaging Guidelines



Kit Components:

2- Freezer Blocks
1- 95kPa bag
1- Swab Pack
1- M4RT Media
1- Lab Form 275

Kits can be ordered by calling (502) 564-4446 or by using the Requisition for Lab Kits at http://chfs.ky.gov/dph/info/lab



Break off swab into transport media

Place tube inside bag with absorbent

Place sample bag on top of frozen freezer blocks and replace styrofoam lid.

Place Lab Form 275 on top of closed styrofoam box

Close box and place appropriate label on top of the box

Appendix 7

Laboratory and Surveillance Key Personnel

Emily Adkins, RN
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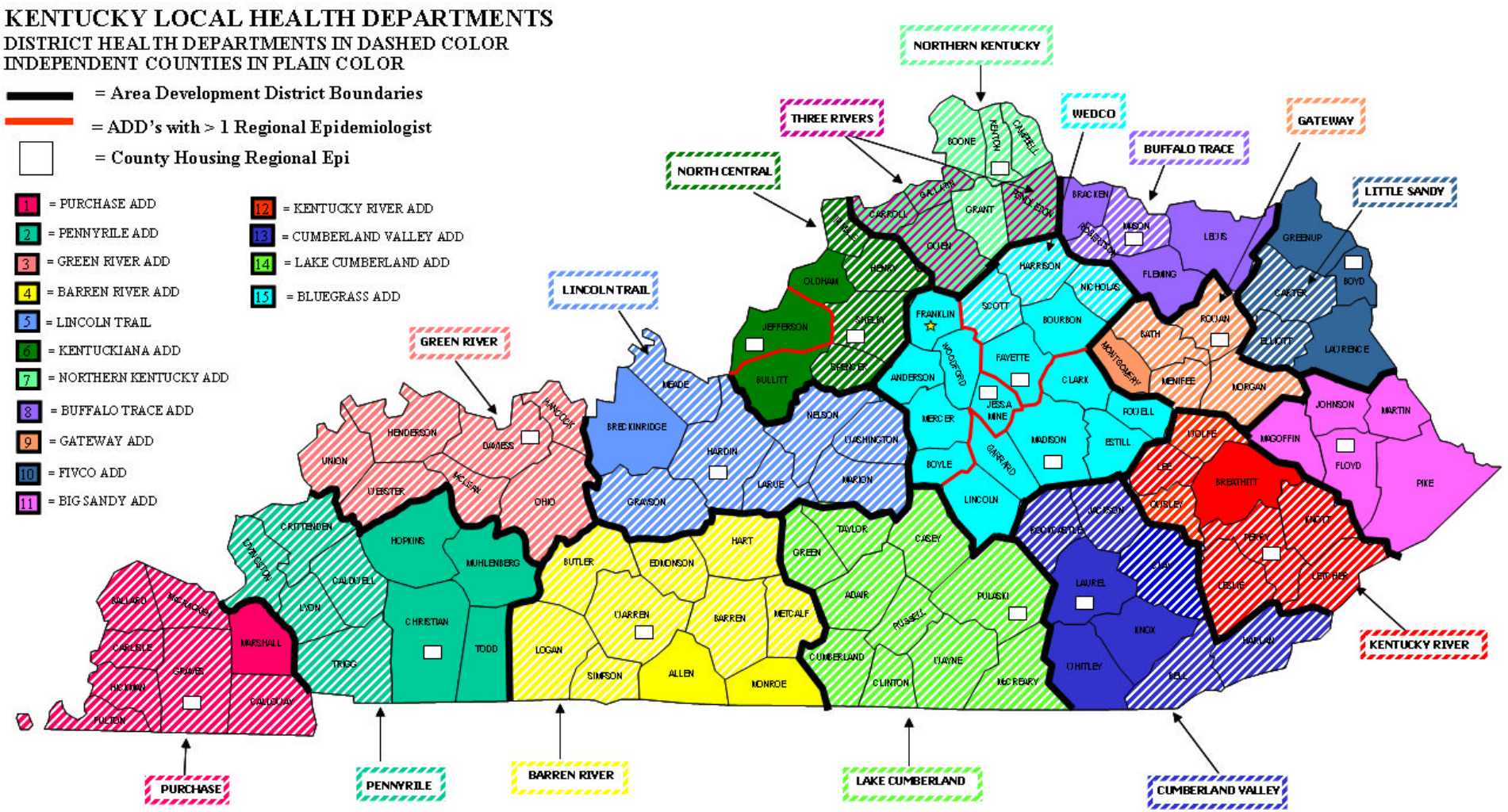
Appendix 8
KY Regional Epidemiologists



Barren River Srihari Seshadri Barren River District Health Deaprtment 1109 State St. P.O. Box 1157 Bowling Green, KY 42101-1157 Phone: (270) 781-8039 Fax: (270) 796-8946 Email: Srihari.Seshadri@ky.gov	**Cumberland Valley** Marion Pennington, DVM Cumberland Valley District Health Department 103 Cher-lyn Lane P.O. Box 1269 London, KY 40741 Phone: (606) 864-4764 Fax: (606) 877-5490 Email: MarionR.Pennington@ky.gov	**Little Sandy** Kristy Bolen Ashland/Boyd County Health Department 2924 Hold Street P.O. Box 4069 Ashland, KY 41105-4069 Phone: (606) 329-9444 Fax: (606) 324-5423 E-mail: KristyM.Bolen@ky.gov
Big Sandy Lyle Snider Floyd County Health Department 283 Goble Street Prestonsburg, KY 41653 Phone: (606) 436-8860 Fax: (606) 886-9318 E-mail: Lyle.Snider@ky.gov	**Gateway** Sally Trent Gateway District Health Department Grudgell Avenue P.O. Box 555 Owingsville, KY 40360 Phone: (606) 674-6396 Fax: (606) 674-3071 E-mail: SallyJ.Trent@ky.gov	**North Central** Vinay Chiguluri North Central District Health Department 1020 Henry Clay Street Shelbyville, KY 40065 Phone: (502) 633-1243 Fax: (502) 633-7658 E-mail: Vinay.Chiguluri@ky.gov
Bluegrass 1 Judy Collins Madison County Health Department P.O. Box 1208 Richmond, KY 40476-1208 Phone: (859) 626-4259 Fax: (859) 623-5910 E-mail: Judy.Collins@ky.gov	**Green River** Janie Cambron Green River District Health Department 1600 Breckenridge Street P.O. Box 309 Owensboro, KY 42303 Phone: (270) 852-5593 Fax: (270) 926-9862 E-mail: JanieC.Cambron@ky.gov	**Louisville Metro** Carl Hall Louisville Metro Department of Public Health & Wellness 400 East Gray Street Louisville, KY 40201 Phone: (502) 574-6699 Fax: (502) 574-6588 E-mail: Carl.Hall@louisvilleky.gov
Bluegrass 2 Andy Waters Lexington/Fayette County Health Department 650 Newtown Pike Lexington, KY 40508 Phone: (859) 231-9791 Fax: (859) 288-2359 E-mail: AndrewD.Waters@ky.gov	**Kentucky River** David Reese Kentucky River District Health Department 441 Gorman Hollow Road Hazard, KY 41701 Phone: (606) 439-2361 Fax: (606) 439-0870 E-mail: DavidR.Reese@ky.gov	**Northern Kentucky** Scott Bowden Northern Kentucky District Health Department 610 Medical Village Drive Edgewood, KY 41017 Phone: (859) 363-2033 Fax: (859) 578-3689 E-mail: Scott.Bowden@ky.gov

Bluegrass 3	Lake Cumberland	Pennyrile
Jennifer Methvin Jessamine County Health Department 215 East Maple St. Nicholasville, KY 40356 Phone: (859) 885-4149 Fax: (859) 885-1863 E-mail: JenniferN.Methvin@ky.gov	Jasie Logsdon Lake Cumberland District Health Department 500 Bourne Avenue P.O. Box 800 Somerset, KY 42702 Phone: (606) 678-4761 Fax: (606) 678-2708 E-mail: JasieK.Logsdon@ky.gov	Sri Pasupulati Christian County Health Department 1700 Canton Street P.O. Box 647 Hopkinsville, KY 42240-0647 Phone: (270) 887-4160 Fax: (270) 887-4165 E-mail: Sri.Pasupulati@ky.gov
Buffalo Trace	**Lincoln Trail**	**Purchase**
David Day Buffalo Trace Health Department 120 W. Third Street P.O. Box 70 Maysville, KY 41056 Phone: (606) 564-9447 Fax: (606) 564-7696 E-mail: DavidL.Day@ky.gov	Ashoka Indukuri Lincoln Trail District Health Department 1222 Woodland Drive Elizabethtown, KY 42702 Phone: (270) 769-1601 Fax: (270) 765-7274 E-mail: AshokaR.Indukuri@ky.gov	Mary Tooms Purchase District Health Department 307 North 7th Street Mayfield, KY 42066 Phone: (270) 247-1490 Fax: (270) 575-5458 E-mail: MaryR.Tooms@ky.gov

Appendix 9

KY Electronic Death Registry Implementation Plan

In a continuing effort to modernize Kentucky's Office of Vital Statistics (OVS), OVS and the Office of Information Technology (OIT) have partnered to conceive of and implement an overarching automated system called the Kentucky Vital Events Tracking System (KVETS). The system will help effectively and efficiently create, track, and maintain all vital records in the commonwealth. Joined by the Public Health Preparedness Branch, the responsible entities recognize the importance of possessing a statewide mechanism which would quickly and easily integrate vital record registrations, certifications, and health statistics. Such a mechanism would be especially crucial in the event of a surge in deaths which might be caused by an influenza pandemic.

Fortunately, the three groups collaborating on this project have a long history of working together and are all well-placed within the infrastructure of the Kentucky Cabinet for Health and Family Services to continue effective collaboration. OVS and the Public Health Preparedness Branch are strategically located side-by-side under the aegis of the Division of Epidemiology & Health Planning, within the Department for Public Health. OIT, a trusted partner, has been instrumental in assisting in the development of a number of electronic data systems for the division, including the Disease Surveillance Module of the Kentucky Electronic Public Health Records System and a prototype of the K-HELPS system (Kentucky Health Emergency Listing of Professionals for Surge) which registers and credentials medical volunteers for disasters.

As a current grantee of the Public Health Emergency Cooperative Agreement , Kentucky is in an excellent position to fully optimize an award for this demonstration project because: 1) the state's medium size and commonly shared demographics would make a successful project here generalizable to a wide range of other states, 2) electronic mortality reporting is the next logical step of progression in implementing the state's vital events systems plan, 3) the state legislature has already paved the way for the acceptance of electronic signatures and documents, and 4) the groundwork has been laid for input and future cooperation from stakeholders in the process who would ultimately determine the project's success.

Over 4.2 million people live in Kentucky, making the state the 26th most populous in the nation. Seventeen other states and Puerto Rico have similar-sized populations that vary from 2-6 million. In terms of the age group that has the highest death rate, about 12.8 percent of the population is age 65 years and older, which is just slightly higher than the national average. The state experiences nearly 40,000 deaths each year and issues about 230,000 certified copies of death certificates yearly, placing its volume in the mid-range as compared to other states. All deaths are registered and certified in a central vital records office at the state capital, known as the Office of Vital Statistics (OVS). This consolidation of work processes through a single authority lends itself well to maintaining control of processes, which will be required when instituting a new statewide electronic reporting system.

From a geographic perspective, the state contains both urban, industrialized centers (over half of the state's citizens live within the "golden triangle" formed by the three metro areas) and sprawling rural areas that are sparsely populated, creating a spectrum of conditions that could make Kentucky's demonstration project more readily replicable in other states. In addition, the state is uniquely situated in the heartland of the country and borders 7 other states, which provides greater opportunities for shared information and information systems across jurisdictional lines.

Kentucky hopes to take advantage of an award from this grant opportunity by continuing to utilize the latest electronic technology to achieve the next logical progression in our scheme: accurate and timely collection, tracking and registration of deaths. The initial phase of our plan to build a vital events tracking system began with the electronic transference of birth data from birthing hospitals in September 2006. At that time OIT collaborated with OVS to implement a web-based Internet application, named the Kentucky Certificate of Birth, Hearing, Immunization and Lab Data (KY-CHILD), in all 56 birthing hospitals throughout the state. This module is used by birthing facilities to electronically capture and submit a variety of data pertaining to the birth of a newborn. Due to the joint efforts of the Cabinet's technology and vital records teams, the software application received national recognition in June 2007 when it won a coveted 2007 Intergovernmental Solution Award from the American Council for Technology at its annual Management of Change Conference.

Since the development of KY-CHILD, CHFS OIT and OVS teams have not rested on their laurels. In January 2008, they jointly implemented the foundational component of a single integrated web-based application for vital records. Known as the Kentucky Vital Events Tracking System (KVETS), phase one of KVETS sets the stage for the development and implementation of independent but well integrated modules for electronic registration of birth, death, divorce and marriage on a single platform. Carrying out the first phase of KVETS has already modernized OVS's birth registration system even further by providing significant improvements in electronic searches, printing of certificates, amendments and accounting.

Shortly after KVETS was put in place, the Kentucky team worked closely with the National Association of Public Health Statistics and Information Systems (NAPHSIS) to implement the association's Electronic Verification of Vital Events (EVVE) system. This web-based system now allows for inter-jurisdictional data exchanges of Kentucky's birth data, in addition to allowing Kentucky to access birth data from other states that are also connected to EVVE.

Development and execution of these recent web-based applications has allowed Kentucky to form a knowledgeable task force that is adept at developing and implementing modernized web-based applications and databases for OVS. In addition, these efforts have helped establish a robust and scalable hardware infrastructure that is well equipped to accommodate and support additional OVS applications. Thus, in terms of both infrastructure and experience, Kentucky CHFS/OVS is optimally positioned for the development and implementation of the proposed EDRS.

Fortunately, the state legislature has assisted by creating a climate that is favorable to developing and operating an EDRS. During the 2000 legislative session, the Kentucky General Assembly enacted Kentucky Revised Statute (KRS) 369.107 which permits the acceptance of electronic signatures on official documents. Moreover, the 2005 General Assembly again addressed electronic signatures in KRS 369.118 by giving the state's own information technology architects the authority to specify the manner and format in which electronic signatures are to be administered. In summary, then, the legislature's foresight removed any previously existing or potential legal barriers to realizing electronic death registration in the state.

Kentucky's plan is to replace the current paper-based death registration system with a fully functional, secure, Public Health Information Network (PHIN)-compliant Electronic Death Registration System (EDRS). This concept could be adapted by other states. The EDRS will be developed using state-of-the-art web based technology with advanced data validation techniques and real-time data interface capabilities. Realization of a fully functional EDRS will improve the efficiency and effectiveness of the electronic mortality reporting by improving timeliness of receipt of death data by NCHS and others as well as strengthening data quality. Kentucky's vision of an EDRS comprises a web-based solution with two distinct components. These include 1) an Internet application for funeral directors and medical certifiers that allows for electronic collection and transmission of death data to OVS and 2) an Intranet system to be utilized by OVS personnel for electronic processing of death data.

Role-based security will be implemented to allow different user groups comprised of funeral directors and medical certifiers to access the EDRS, in order to perform their unique functions. Using the electronic death reporting module, the state's funeral directors and medical certifiers will be able to directly enter information on a decedent into a web-based Internet application that would contain system-wide edits for improving data completeness and quality. Various electronic capabilities, including e-mail and automatic workflows associated with each user group will be provided for transmission and submission of death related data so that data can be shared and tracked by all parties. The state's approximately 9,300 physicians, 2,100 licensed funeral directors and 425 coroners could access the EDRS module via the use of web services from any home or business computer. Kentucky estimates that the vast majority of funeral directors and certifiers have Internet access in a commonly frequented venue.

Via the web-based EDRS, death data would be instantaneously transmitted to the central office of OVS for processing by OVS personnel, once the data are ready for submission by funeral directors and medical certifiers. OVS personnel could immediately access this data electronically via the EDRS module of the KVETS application within seconds of its submission. The EDRS module would also allow OVS personnel to electronically review and approve death certificates prior to assignment of a State File Number (SFN). An automatic printing process is anticipated for printing of death certificates. In addition, OVS personnel will have the capability to electronically reject erroneous certificates. These rejections will be seamlessly and instantaneously transmitted to the funeral

directors or medical certifiers for electronic corrections and re-submissions of the death certificates via the Internet application.

To this end, the process of networking with and creating buy-in among the primary stakeholders--- funeral directors, medical certifiers and OVS staff-- has already begun. In May 2007, a "Death Registration Stakeholders Workgroup" was created at the behest of state administration officials. The group was charged with bringing together a diverse collection of stakeholders including the Kentucky Funeral Directors Association, the Kentucky Coroners Association, the Kentucky Medical Association, cabinet legal staff, and internal OVS staff, in order to set about "modernizing the death registration process to include electronic records transference and tracking." Representatives from NAPHSIS and NCHS also attended the first meeting of the group. In addition to supporting the formal workgroup and its subgroups, OVS and OIT personnel have also participated in several stakeholder meetings consisting of funeral directors and medical certifiers in an effort to better understand and document their current business processes. As a result, tangible progress has been made in developing a united approach that is embodied in the current EDRS plan. A foundation has also been laid for future steps, which will include the marketing of EDRS to stakeholders and use by them.

With the capability of electronic submission at the fingertips of the frontline users, transmission of data on cause of death and demographics of death occurrences becomes an invaluable tool in the reporting, classification, and intervention of deadly outbreaks like pandemic influenza. This proposed web-based solution will dramatically improve the timeliness and accuracy of death data reporting in the commonwealth. For death certificates filed electronically, OVS could deem them official within two days, compared to the average of twelve days under the current process/system. Overall, the processing time from death to entry into an electronic file would be reduced from an average of five weeks to less than four days.

Moreover, the time savings in processing would also result in much earlier notification of federal partners about the number and causes of deaths in a pandemic. The quality and standardization of death data for NCHS reporting and disease surveillance would be improved, too--- through the built-in editorial features described above and adherence to PHIN standards. PHIN vocabulary standards for vital records will be incorporated into the EDRS once standards are published by the CDC. To assure that proper data validation rules in accordance with NCHS are implemented within the EDRS, OIT and OVS personnel have been working very closely with NAPHSIS to define validation and edit rules for a Public Health Information Network (PHIN)-compliant EDRS. Among other validation rules, the proposed EDRS will provide real time interfacing capabilities with the Social Security Administration (SSA) via a NAPHSIS application to ensure proper validation of social security numbers. Thankfully Kentucky already has a strong ongoing working relationship with the National Association for Public Health Statistics and Information Systems (NAPHSIS) and will continue to rely on NAPHSIS guidance. Once the State and Territorial Exchange of Vital Events System (STEVE) is deployed nationally, death data could be transmitted from Kentucky's EDRS to NCHS via that interface during a pandemic.

By achieving all these efficiencies and improving accuracy, OVS would also be infinitely more equipped to handle pandemic death surges with fewer employees and might even be able to redirect resources during a disaster to focus on helping to speed up data tracking and the relationships between funeral directors and medical certifiers. If available, staff time could also be used to smooth the transition to bring a new group of medical certifiers on-board. Though according to Kentucky law, licensed physicians, dentists, chiropractors and coroners can all serve as medical certifiers for completing and signing the death certificate, in practice only physicians and coroners usually perform this function. Anticipating a future pandemic, however, the state's Public Health Preparedness Branch is exploring providing pre-event training on medical certification of death certificates via EDRS to dentists and chiropractors, so that the pool of certifiers could easily be expanded within EDRS in case of a death surge.

Finally, the rapid communication mechanism created by EDRS will allow faster response to specific geographical areas within the state that might be most impacted by a pandemic. The accumulation of the data from this statewide initiative provides an opportunity to decrease the time needed to detect and classify deaths in regional areas, facilitating the initiation of mass fatality plans. Faster and more accurate communication about deaths also could speed reaction and countermeasure support by first responders. Perhaps most importantly, EDRS could further serve as the foundation for restoring pre-event levels in health services and public safety by reducing the time to process decedents' paperwork, identifying areas that are experiencing declines in deaths, and providing data that would direct recovery efforts.

Although the grant award is not expected to cover the maintenance period that will ensue after the EDRS is fully employed, provisions for on-going sustainability of the system have been made as part of Kentucky's approach. Resources that will be saved from scaling back a third-party contract currently required for death entry will be used instead to help maintain the EDRS. Automation of processes brought about by the EDRS would also allow OVS to operate with fewer personnel. Savings from salaries could be used towards on-going maintenance costs.

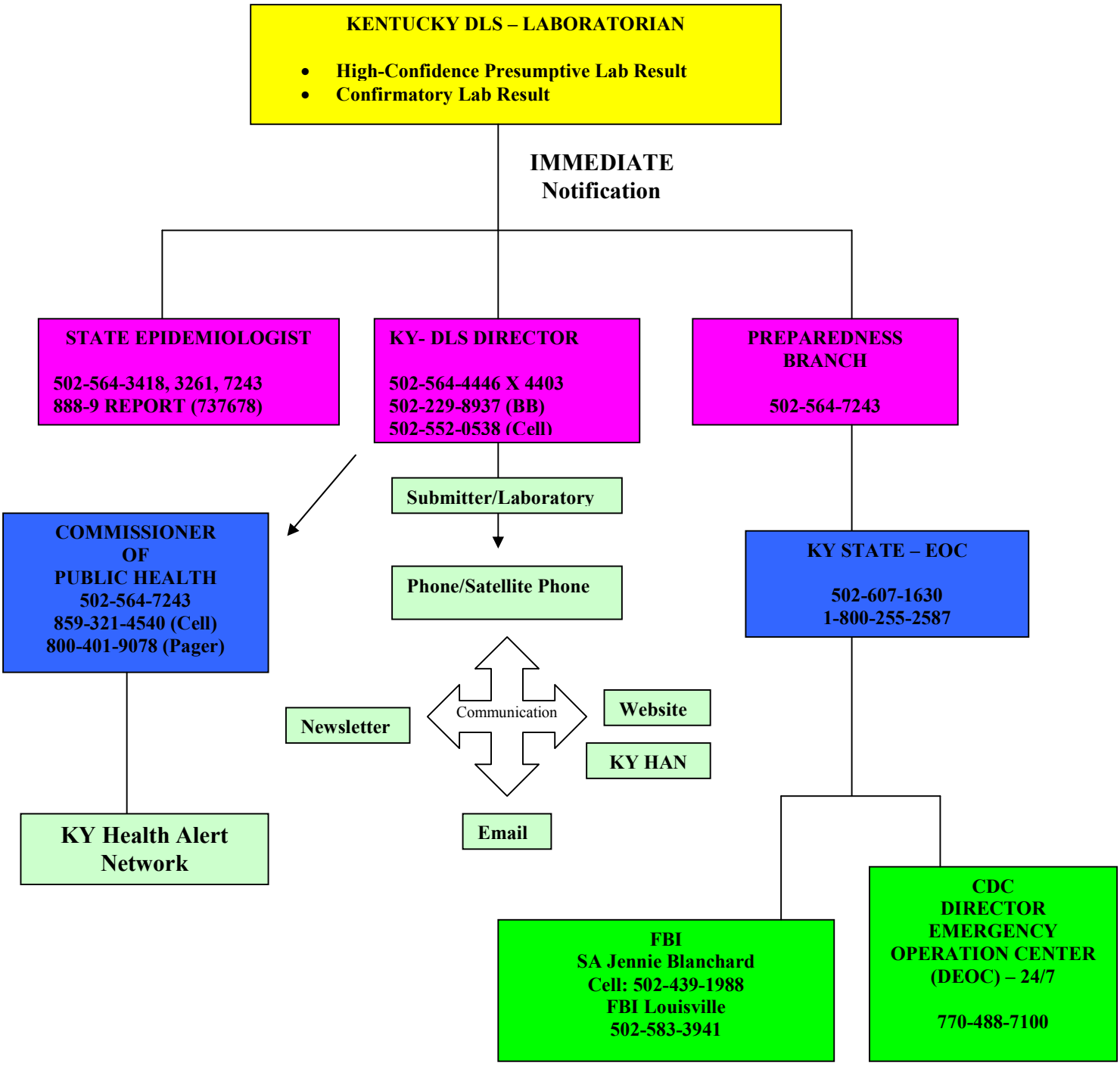
Appendix 10

Laboratory Call-Down Procedure for KY CHFS, DPH, DLS

NOTIFICATION PLAN FOR POTENTIAL PUBLIC HEALTH INCIDENTS

The Kentucky DLS has a collaborative partnership with CDC's Laboratory Response Network (LRN) sharing their strategy to provide a timely response to potential bioterrorism threats or public health emergencies and to provide rapid notification to public health officials of significant laboratory results for biological threat agents. The LRN defines a potential public health threat "as an emergency situation or any other testing of credible suspect material requiring use of LRN algorithms, assays, and reagents." Below is the Kentucky DLS notification algorithm for Kentucky public health incidents.

PUBLIC HEALTH INCIDENT RESPONSE – NOTIFICATION ALGORITHM



Source: lrn.notificationpolicy3120606

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NAME		*ADDRESS*	*CITY*	*PHONE*	*FAX*	*CONTACT PERSON*	*EMAIL ADDRESS*
BT 8/1/02	**Appalachian Regional Healthcare**	**103 Medical Center Drive**	**HAZARD 41701**	**606-487-7452 Lab-606-487-7461**	**606-487-7458**	**Larry Johnson**	**ljohnson@arh.org** **mpotter@arh.org**
	Baptist Hospital East	**4000 Kresege**	**LOUISVILLE 40207-4676**	**502-896-7056**	**502-897-8051**	**Karen Bartlett**	**Karen.bartlett@bhsi.com** **Betty.curry@bhsi.com**
BT 7/18/02 11/21/02 P	**Baptist Hospital Northeast** **No longer does micro**	**1025 New Moody Ln PO BOX 20164**	**LAGRANGE 40031**	**502-222-3365**	**502-222-3401**	**Judy Lawhorn**	**jlawhorn@bhsi.com**
BT 4/24/02 5/9/02	**Baptist Regional Medical Center**	**1 Trillium Way**	**CORBIN 40701**	**606-523-8534 528-1212 (4503) Leila**	**606-523-8725**	**Carolyn Yaden** **Leila Cromer**	**cyaden@bhsi.com** **lcromer@bhsi.com**
	Blanchfield Community Hospital	**650 Joel Drive**	**Fort Campbell 42223-5349**	**270-798-8785**	**270-798-8544**	**Annie Baker**	**Annie.baker@se.amedd.army.mil** **Chery.watson@se.amedd.army.mil**
BT 11/21/02	**Bowling Green Med. THE MEDICAL CENTER, CLINICAL LAB**	**P.O. BOX 90010** **250 Park Street**	**BOWLING GREEN 42101-1760**	**270-745-1313**	**270-745-1325**	**Jean Craig**	**JECRAIG@MCBG.ORG**
BT 7/18/02	**Breckinridge Memorial Hospital**	**1011 Old HWY 60**	**HARDINSBURG 40143**	**270-756-6541**	**270-756-6591**	**Ken Walden**	**kwalden@breckhealth.org** **dlewis@breckhealth.org**
BT 11/07/02 P	**Caldwell Co. Hospital**	**101 Hospital Dr.**	**PRINCETON 42445-2301**	**270-365-0456**	**270-365-0453**	**Marlene Thorpe**	**mthorpe@caldwellhosp.org**
BT 7/25/02 8/1/02 P	**Caritas Medical Center (St. Mary and Elizabeth)**	**1850 Bluegrass Ave.**	**LOUISVILLE 40215**	**502-361-6526** **6496**	**502-361 6579**	**Kim Sipes**	**Kim.sipes@jhsmh.org**

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BT 5/8/02 11/14/02 P	**Caverna Memorial Hospital**	**PO BOX 120** **1501 South Dixie Hwy**	**HORSE CAVE 42749**	**270-786-2191 EXT.67**	**270-786-5086**	**James Jolly**	**jamesjolly@scrtc.com**
BT 5/9/02 P	**Central Baptist Hospital**	**1740 Nicholasville Rd.**	**LEXINGTON 40503**	**859-260-5139 859-260-6192**	**859-260-6930**	**BJ Correll Cheryl Colliver**	**bcorrell@bhsi.com**
BT 6/10/03	**Clark Regional Medical Center**	**1107 W. Lexington Ave.**	**WINCHESTER 40391-1169**	**859-745-3436**	**859-745-3676**	**Amy Kinney**	
BT 11/7/02 P	**Crittenden Health System**	**PO Box 386 HWY60 South**	**MARION 42064**	**270-965-1058**	**270-965-1088**	**Shawna Sunderland**	**shawnas@crittenden-health.org**
BT 4/24/02 11/7/02 P	**Cumberland Medical Laboratory**	**PO Box 3310** **(205 Professional Plaza)**	**SOMERSET 42564-3310**	**606-678-8800**	**606-679-5238**	**Charlotte Leis**	**Cleis1@newwavecomm.net**
BT 11/7/02 P	**Ephraim McDowell Regional Med. Center**	**217 S. Third St.**	**DANVILLE 40422**	**859-239-2262** **859-239-1000 General**	**859-239-6737**	**Connie Denny**	**rscott@emrmc.org codenny@emrmc.org**
BT 5/09/02 P	**Flaget Memorial Hospital**	**4305 New Shepardsville Rd. Bardstown, KY 40004**	**BARDSTOWN 40004**	**502-350-5115**	**502-350-5116**	**Mary Ann Schentrup**	**mas@flaget.com**
BT 6/03/03 6/10/03	**Frankfort Regional Medical Center**	**299 Kings Daughter Dr.**	**FRANKFORT 40601**	**502-226-7585**	**502-226-7939**	**Carole Hackett**	**Carole.Hackett@hcahealthcare.com**
BT 7/25/02 8/1/02 P	**Georgetown Comm. Hospital**	**1140 Lexington Rd.**	**GEORGETOWN 40324**	**502-868-1280**	**502-868-1283**	**Debbie Rodgers**	**Debbie.Rodgers@lifepointhospitals.com**

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BT 5/9/02 P	**Greenview Regional Hospital**	**1801 Ashley Circle**	**BOWLING GREEN,42104-3362**	**270-793-2075**	**270-793-2064**	**Carol Greenwood**	**Carol.greenwood@hcahealthcare.com**
BT 5/8/02 11/14/02 P	**Hardin Memorial Hospital Main Lab**	**913 N Dixie Ave.**	**Elizabethtown 42701**	**270-706-1582**	**270-706-1035**	**Gwen Wilkins**	**gwilkins@hmh.net**
BT 4/24/02	**Harrison Memorial Hospital**	**Millersburg Pike**	**CYNTHIANA 41031**	**859-235-3681**	**859-235-3601**	**Shawna Goble**	**sgoble@hmhosp.org**
BT 8/1/02	**Highlands Regional Medical Center**	**US 23 North PO BOX 668**	**PRESTONBURG 41653**	**606-886-8511**	**606-886-7779**	**Rachel Crider**	**rcrider@hrmc.org**
BT 6/03/03 P	**Ireland Army Hospital**	**851 Ireland Dr.. MCXM-LAB-DP**	**FORT KNOX *40121***	**502-624-9380**	**502-624-9706**	**Debbie Denton Mike Young**	**deborah.denton@na.amedd.army.mil Michael.young3@na.amedd.army.mil**
	Jackson Purchase Medical Center	**1099 Medical Center Circle**	**Mayfield 42066**	**270-251-4115**	**270-251-4118**	**Bruce Rives Donna Moses**	**Bruce.rives@lpnt.net Donna.moses@lpnt.net**
BT 5/09/02 6/03/03	**James B Haggin Memorial Hospital**	**464 Linden Ave.**	**HARRODSBURG 40330**	**859-7345-441**	**859-733-4844**	**Kim Russell**	**krussell@hagginhosp.org**
BT 7/18/02 P LRN	**Jennie Stuart Medical Center**	**320 West 18th Street**	**HOPKINSVILLE 42240**	**270-887-0113**	**270-887-0149**	**Eddie Gross Gina Hester**	**egross@jsmc.org**
BT 4/24/02 P	**Jewish Hospital**	**100 Abraham Flexner Way**	**LOUISVILLE 40202**	**502-587-4339 502-587-2878(Lab)**	**502-587-4865**	**Tommee Clark**	
BT 7/18/02 6/03/03	**Kindred Hospital Louisville**	**1313 St. Anthony Place**	**LOUISVILLE 40204**	**502-627-1247**	**502-627-1687**	**Michelle Hall**	**michelle_hall@kindredhealthcare.com**

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BT 5/9/02 11/21/02 P	King's Daughter Memorial Hospital	2201 Lexington Ave.	ASHLAND 41101	606-408-4604 Dick - 4033	606-408-4738	Bill Kitchen Dick Edgington	Bill.kitchen@kdmc.net Dick.edgington@kdmc.net
BT 8/01/02 P	Knox Co. Hospital	80 Hospital Drive	BARBOURVILLE 40906	606-546-4175 ext.4093	606-545-5570	Stephanie Mosley	smosley@knoxcohospital.com
BT 8/01/02	Lake Cumberland Regional Hospital	305 Langdon Street	SOMERSET 42501	606-678-3163	606-678-3516	Danny Stephens	
	Lourdes	1530 Lone Oak Rd.	PADUCAH 42003	270-444-2140	270-4442343	Milissa Haygood	mhaygood@lourdes-pad.org
BT 7/25/02 11/21/02	Manchester Memorial Hospital	201 Marie Langdon Drive	MANCHESTER 40962	606-598-5104 X3140	606-598-1894	Martha Smith	martha.smith@ahss.org
BT 5/09/02 11/14/02	Mary Breckinridge Hospital	130 Kate Ireland Drive	HYDEN 41749	606-672-2901 EXT.1153	606-672-3704	Tammy Collett	
BT 6/10/03	Marymount Hospital	East 9TH Street	LONDON 40741	606-877 3781, 3780	606-877-3777	Gale Boggs Vaunene Greene	gboggs@marymount.com
BT 6/03/03 L	Meadowview Regional Medical Center	989 Medical Park Drive	MAYSVILLE 41056-8700	606-759 3158/9	606-759-5211	Elica Barbour Polly White	Elica.Barbour@lpnt.net Polly.white@lpnt.net
Book quiz given	Methodist Hospital	1305 N. Elm St.	HENDERSON 42420	270-827-7140	270-827-7404	Jim Butler	jbutler@methodisthospital.net
	Methodist Hospital Union County	4604 US 60 West	Morganfield 42437	270-389-5165	270-389-5164	Sherri Reneer	sreneer@methodisthospital.net
BT 11/21/02	Monroe Co. Medical Center	529 Cap Harlan Rd.	TOMPKINSVILLE 42167	270-487-9231- ext.186 Lab 1185	270-487-5707	Vicky Barnette	lab@mcmccares.com
	Muhlenberg Community Hospital	440 Hopkinsville St.	Greenville 42345	270-338-8366	270-338-8155	Janice Strader	mchlab@muhlon.com

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BT 8/01/02	**Murray Calloway County Hospital**	**803 Poplar Street**	**MURRAY 42071**	**270-762-1120**	**270-767-3608**	**Pam Keller**	**pkeller@murrayhospital.org**
BT 11/14/02	**Norton Healthcare Laboratory**	**200 East Chestnut St.**	**LOUISVILLE 40202**	**502-629-7864 L-7825**	**502-629-7832**	**Dr. George Buck Donna Thacker**	**Donna.thacker@nortonhealthcare.org**
BT 4/24/02 5/8/02 P	**Ohio Co. Hospital**	**1211 Main St.**	**HARTFORD 42347**	**270-298-5419**	**270-298-5167**	**Sara Hall**	**shall@ohiocountyhospital.com**
BT 8/1/02	**Owensboro Medical Health System**	**811 E Parrish Ave. PO Box 20007**	**OWENSBORO 42303 If using PO Box use 42304-0007**	**270-688-2558 L-2946**	**270-688-2938**	**Rhonda Harris**	**rharris@omhs.org**
BT 11/7/02	**Pattie A Clay Regional Med. Center**	**801 Eastern ByPass**	**RICHMOND 40475**	**859-625-3250**	**859-625-3597**	**Wendy Alford**	**wendyalford@pattieaclay.org**
BT 11/21/02	**Paul B. Hall Regional Medical Center**	**625 James S. Trimble Blvd.**	**PAINTSVILLE 41240**	**606-789-3511 EXT.1239**	**606-788-6425**	**Scott Souther**	**Scott.Souther@PBHRMC.hma-corp.com**
BT 11/7/02	**Pikeville Medical Center**	**911 South Bypass Road**	**PIKEVILLE 41501**	**606-437-3514 ext.3260**	**606-437-2339**	**Don Williamson Nina Reynolds**	**Don.Williamson@pikevillehospital.org Nina.Reynolds@pikevillehospital.org**
BT 11/21/02	**Pineville Community Hospital**	**850 Riverview Ave.**	**PINEVILLE 40977**	**606-337-4288**	**606-337-4289**	**Patricia Brown**	**pbrownpch@bellsouth.net**
BT 6/03/03	**Quest Diagnostics**	**2277 Charleston Dr.**	**LEXINGTON 40505**	**800-366-7522 ext.7340**	**859-293-7406**	**Randall Cheek**	**Randall.W.Cheek@questdiagnostics.com**
BT 11/14/02	**Rockcastle Hospital Laboratory**	**145 Newcomb Ave. PO Box 1310**	**MT VERNON 40456**	**606-256-2195**	**606-256-7711**	**Ruth Blanton**	

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NAME		*ADDRESS*	*CITY*	*PHONE*	*FAX*	*CONTACT PERSON*	*EMAIL ADDRESS*
BT 8/1/02 11/21/02 6/10/03 P	Russell Co. Hospital	153 Dowell Rd. PO Box 1610	RUSSELL SPRINGS 42642	270-866-4141-ext.519	270-866-6632	Lisa Johnson	lrjohnson@russellcohospital.org
BT 5/08/02	Samaritan Hospital	310 South Limestone Street	LEXINGTON 40508	859-226-7090	859-226-7093	Vicky Norton	Vicky.norton@samaritanhospital.com
BT 8/1/02 P	ST Claire Regional Medical Center	222 Medical Circle Dr.	MOREHEAD 40351	606-783-6721	606-783-6726	Donna Fannin	dmfannin@st-claire.org
BT 5/08/02 P	ST Elizabeth Medical Center South Laboratory	1 Medical Village Drive	EDGEWOOD 41017	859-301-2012	859-301-5560	Terry McSorley	tmcsorl@stelizabeth.com
BT 5/9/02 P	ST Joseph Hospital	ONE St. Joseph Drive	LEXINGTON 40504	859-313-1803	859-313-3057	Jamie Adkisson	Jamie_m_adkisson@sjhlex.org
BT 6/03/03	Taylor Regional Hospital	1700 Old Lebanon Rd.	CAMPBELLSVILLE 42718-9662	270-789-5802 CM - 5800	270-789-5870	Wallace Feese Charles Morrison	wfeese@tchosp.org
BT 5/9/02	Three Rivers Medical Center	PO Box 769	LOUISA 41230-0769	606-638-1504	606-638-1517	Diane Martin	Diane_martin@chs.net
BT 11/07/02 6/10/03	TJ Samson Community Hospital	1301 North Race St.	GLASGOW 42141	270-651-4162 sc-4400 jb-4165	270-651-1747	James Brown Sondra Cook-Lab Manager	Prefer to fax scook@tjsamson.org
	Trover Foundation Lab	900 Hospital Drive	Madisonville 42431	270-825-5137	270-825-5826	Sheryl Stockton	sstockto@trover.org
BT 7/18/02 7/25/02	University of Kentucky Clinical Micro Lab	800 Rose Street HA638	LEXINGTON 40536	859-323-8950	859-323-5054	Sue Overman Beth Fountain	Soverma@email.uky.edu

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BT 11/7/02 06/10/03	**University of Louisville Hospital Laboratory**	**530 South Jackson**	**LOUISVILLE 40202**	**502-562-3353**	**502-562-4218**	**Karen George**	**Kareng@ulh.org**
BT 11/7/02	**VA Medical Center Louisville**	**800 Zorn Ave.**	**LOUISVILLE 40206**	**502-287-5536**	**502-287-6265**	**Mark Heckman**	**Mark.heckman@med.va.gov**
BT 8/1/02	**Wayne Co. Hospital**	**166 Hospital Street**	**MONTICELLO 42633-2416**	**606-340-3223**	**606-340-3271**	**Frances Mercer**	**fmercer@waynehospital.org**
BT 7/25/02 P	**Western Baptist Hospital**	**2501 Kentucky Ave.**	**PADUCAH 42003**	**270-575-2796**	**270-575-2616**	**Suzanne Thomas**	**sthomas1@bhsi.com**
BT 5/8/02 P	**Westlake Regional Hospital (CLINICAL LAB)**	**901 Westlake Dr. P.O. Box 1269**	**COLUMBIA 42728**	**270-384-4753 EXT.134**	**270-384-1608**	**Doris Critz**	**dcritz@duo-county.com**